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Dong et al.

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(54) **OFF-LINE SENSING METHOD AND ITS APPLICATIONS IN DETECTING UNDERSENSING, OVERSENSING, AND NOISE**

USPC 600/509, 515-519, 521
See application file for complete search history.

(75) Inventors: **Yanting Dong**, Lexington, KY (US);
Shijie Zhang, Pittsburgh, PA (US);
Deepa Mahajan, Circle Pines, MN (US);
Chenguang Liu, Birmingham, AL (US);
Dan Li, Shoreview, MN (US);
Yayun Lin, St. Paul, MN (US); **Derek D. Bohn**, Woodbury, MN (US)

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(73) Assignee: **Cardiac Pacemakers, Inc.**, St. Paul, MN (US)

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Primary Examiner — Catherine Voorhees

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(74) *Attorney, Agent, or Firm* — Pauly, DeVries Smith & Deffner, LLC

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A61B 5/04 (2006.01)
A61N 1/39 (2006.01)

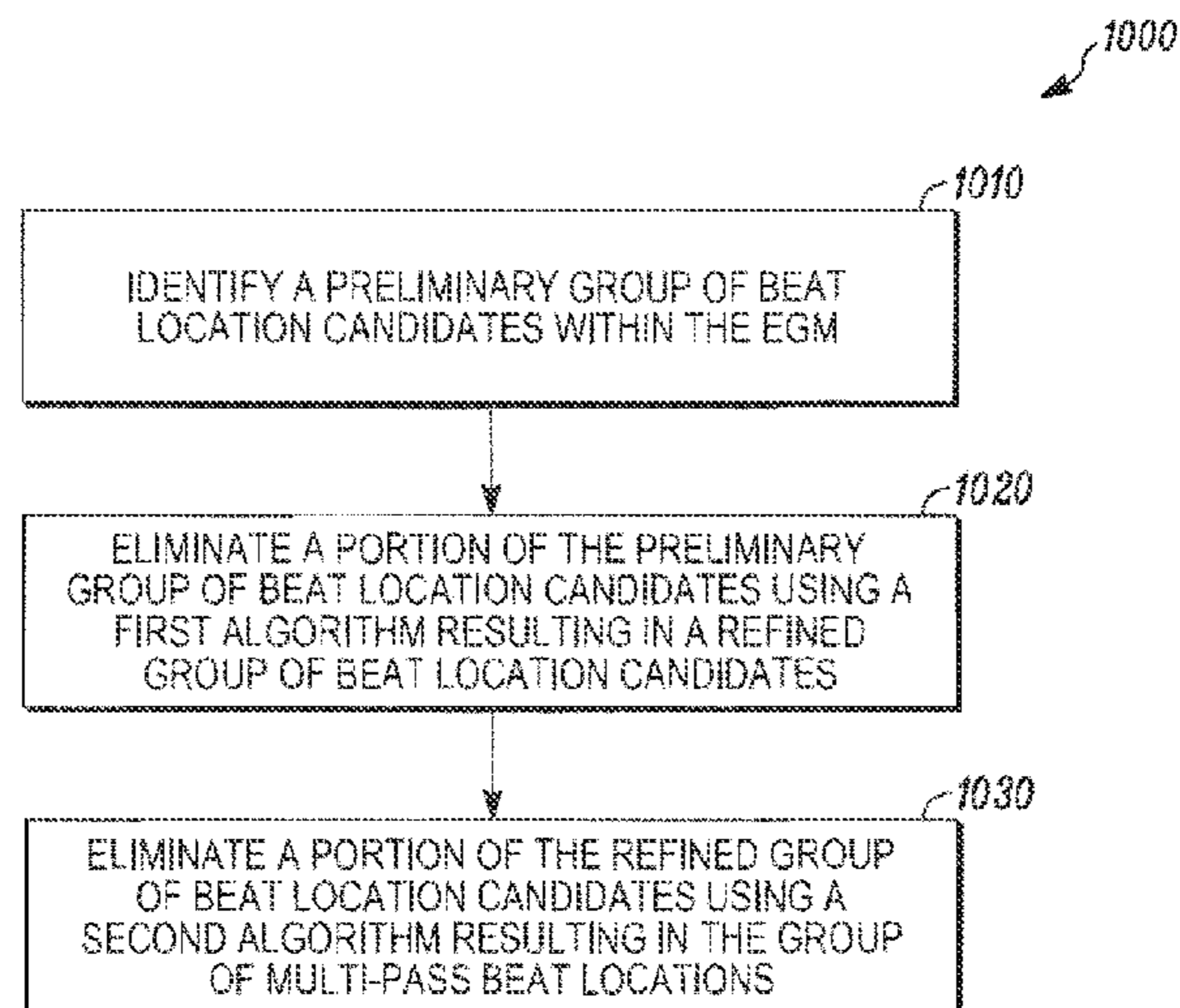
(52) **U.S. Cl.**
CPC **A61B 5/04012** (2013.01); **A61N 1/3937** (2013.01)
USPC **600/509**; **600/510**

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CPC .. **A61B 5/7217**; **A61B 5/0245**; **A61B 5/0452**;
A61B 5/042; **A61N 1/3704**

(57) **ABSTRACT**

A system and method for performing independent, off-line evaluation of event sensing for collected electrograms, comprising: sensing an electrogram using an implantable medical device (IMD); determining locations of heart beats on at least one channel of the electrogram using a multi-pass process, resulting in a group of multi-pass beat locations; storing the electrogram and device-identified beat locations in a memory location; and retrieving the electrogram and device-identified beat locations from the memory location. The multi-pass process determines locations of heart beats on at least a first channel of the electrogram. The device-identified group of beat locations are then compared to the multi-pass group of beat locations identified using the multi-pass method. Based on the comparing step, oversensing of beats, undersensing of beats, or noise from the device can be detected.

4 Claims, 18 Drawing Sheets



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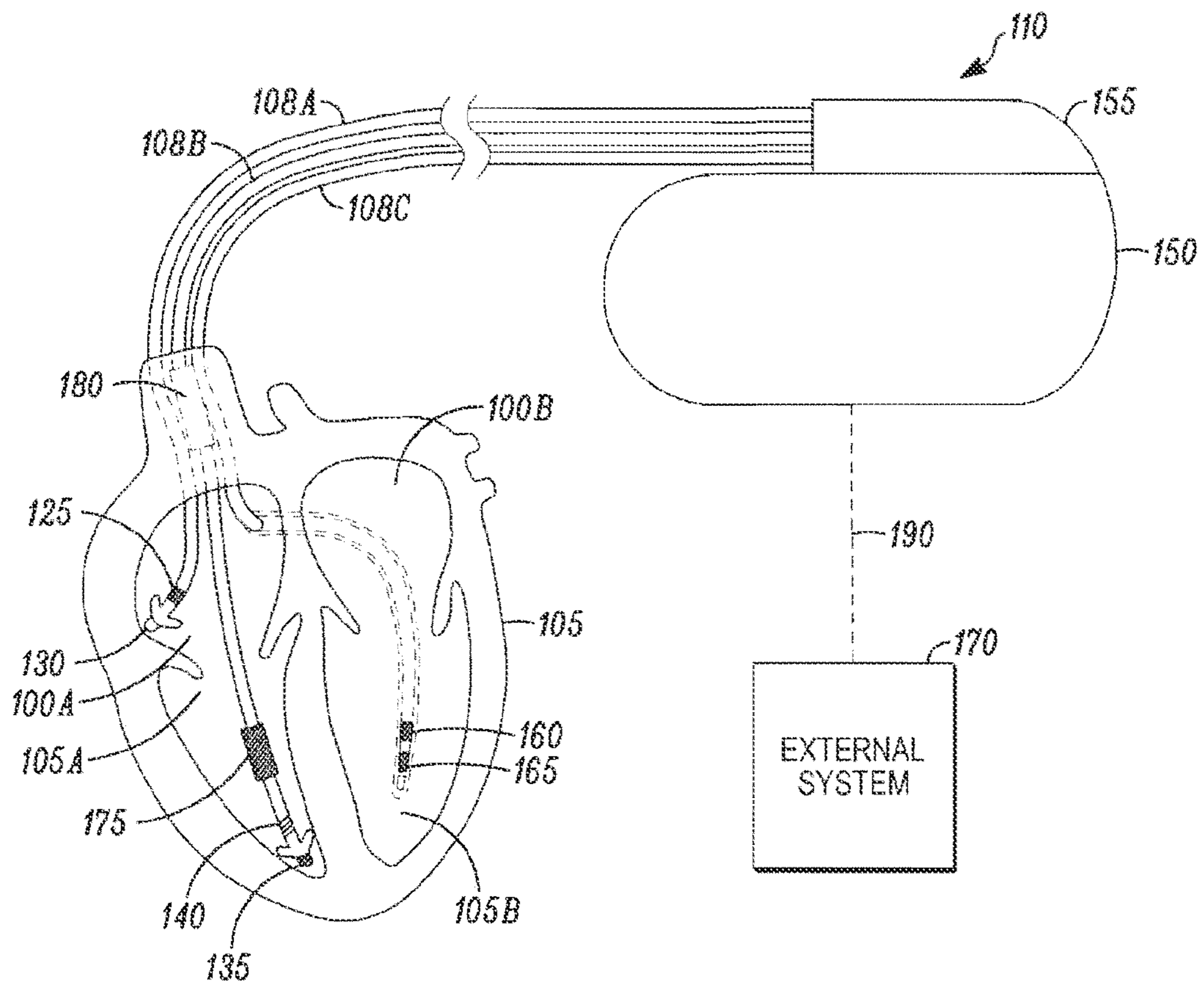


FIG. 1

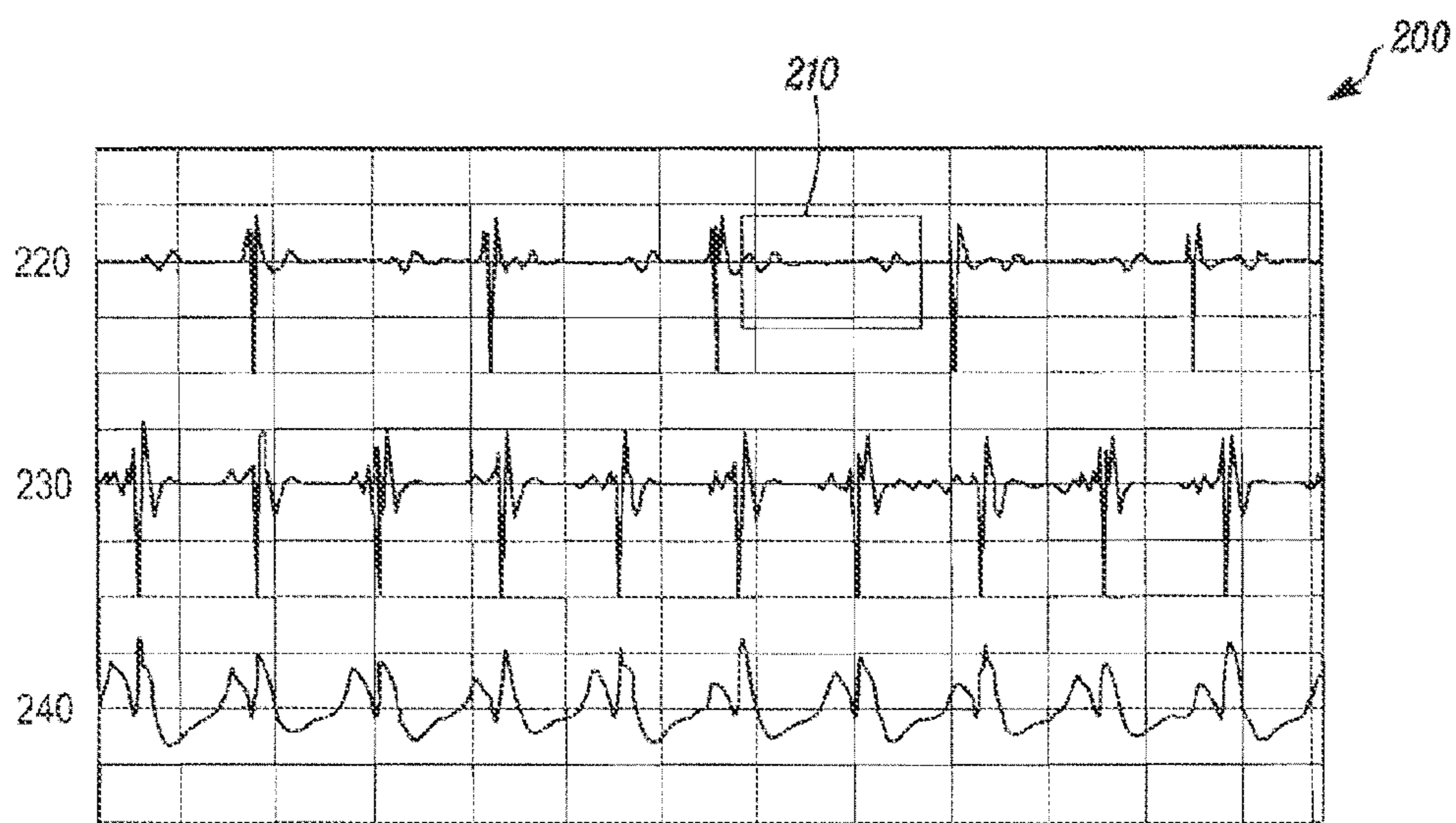


FIG. 2

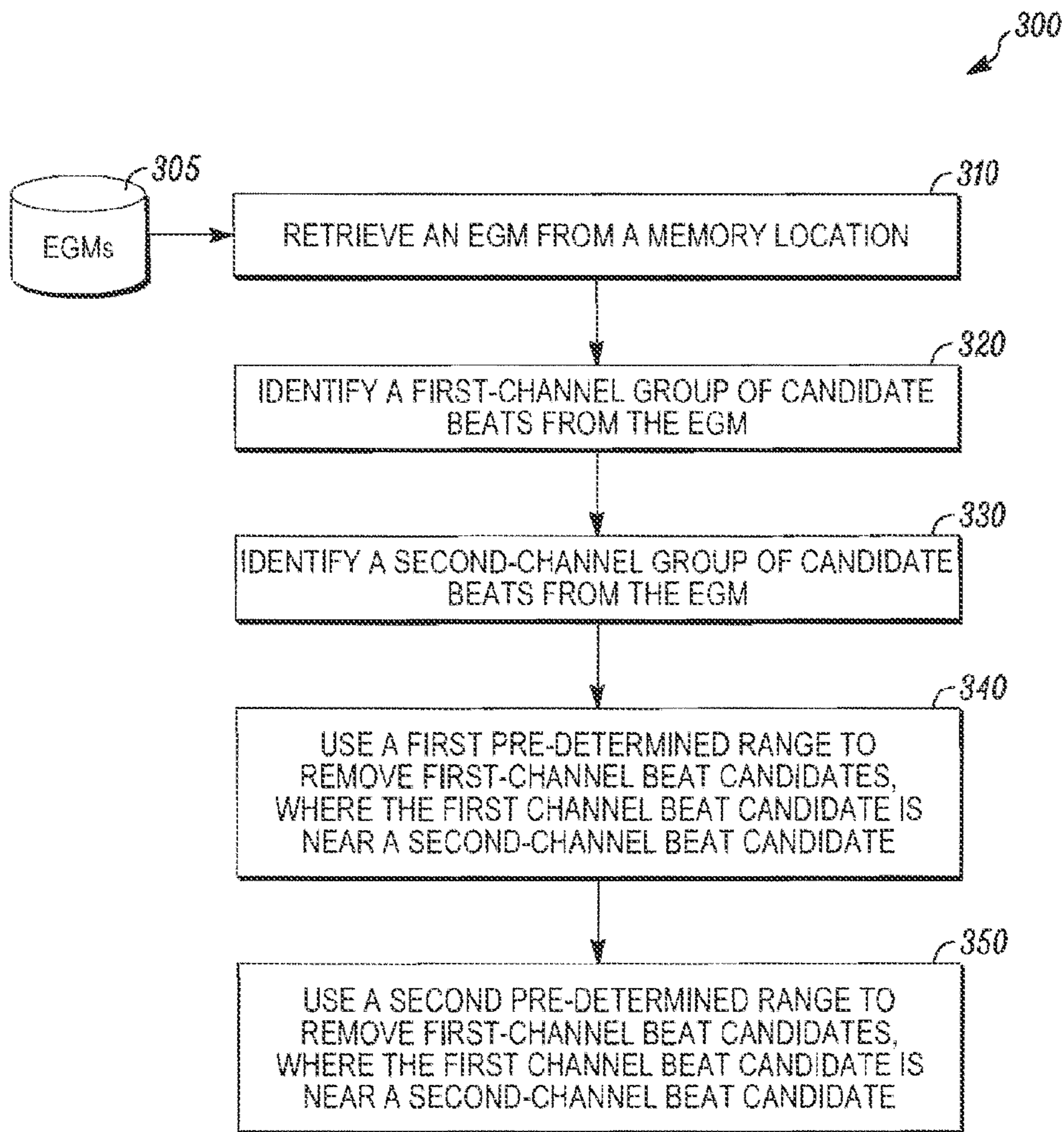


FIG. 3

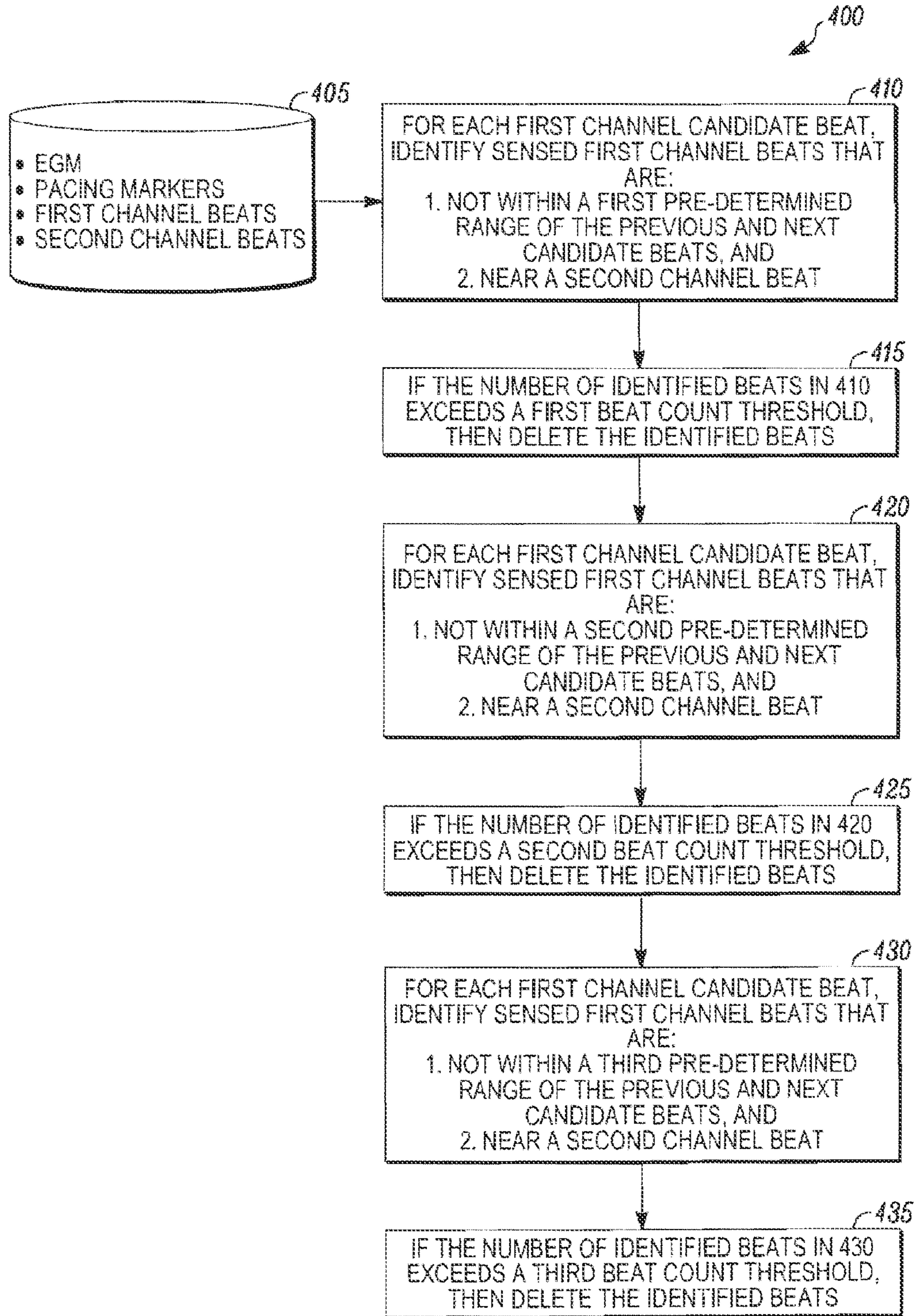


FIG. 4

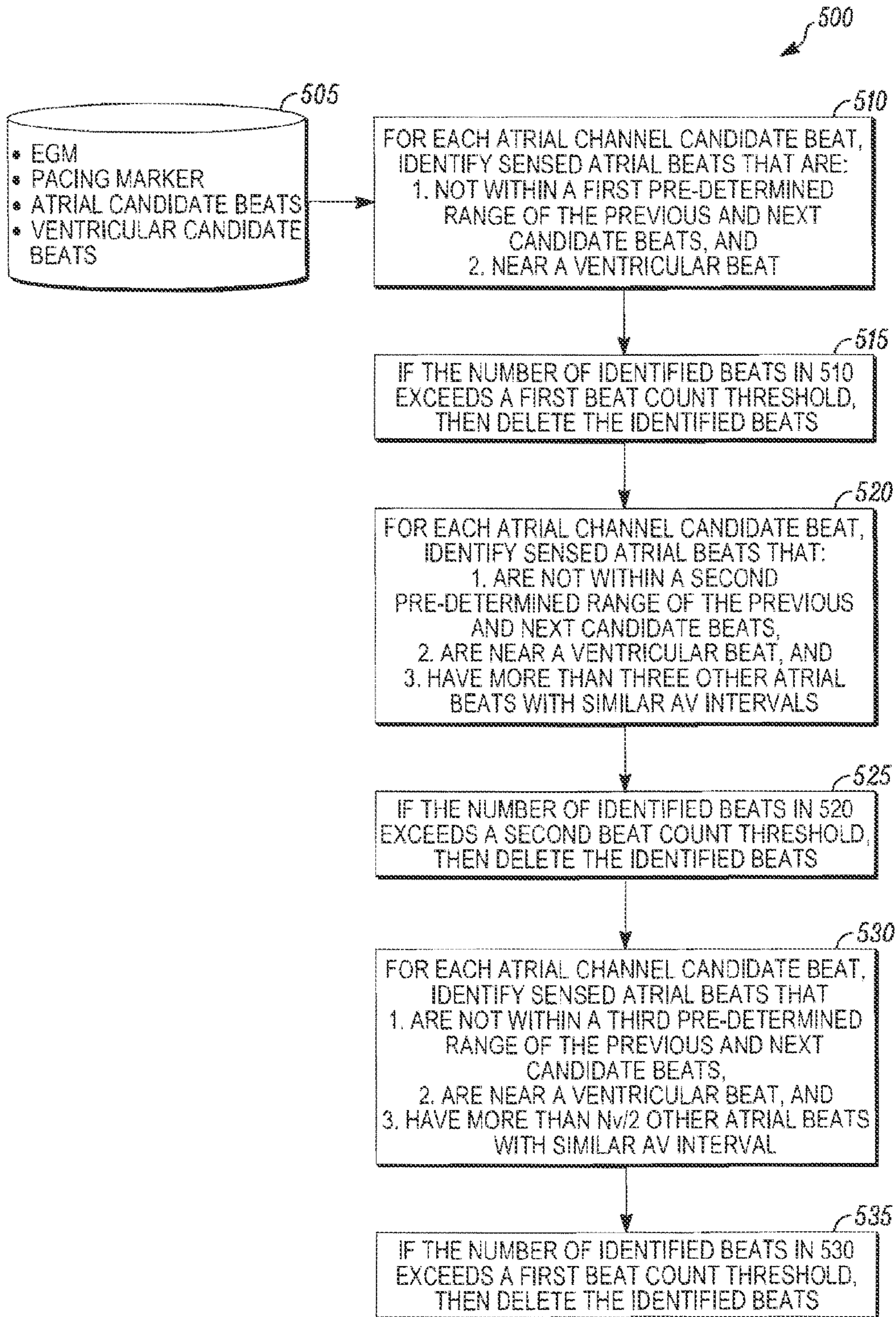


FIG. 5

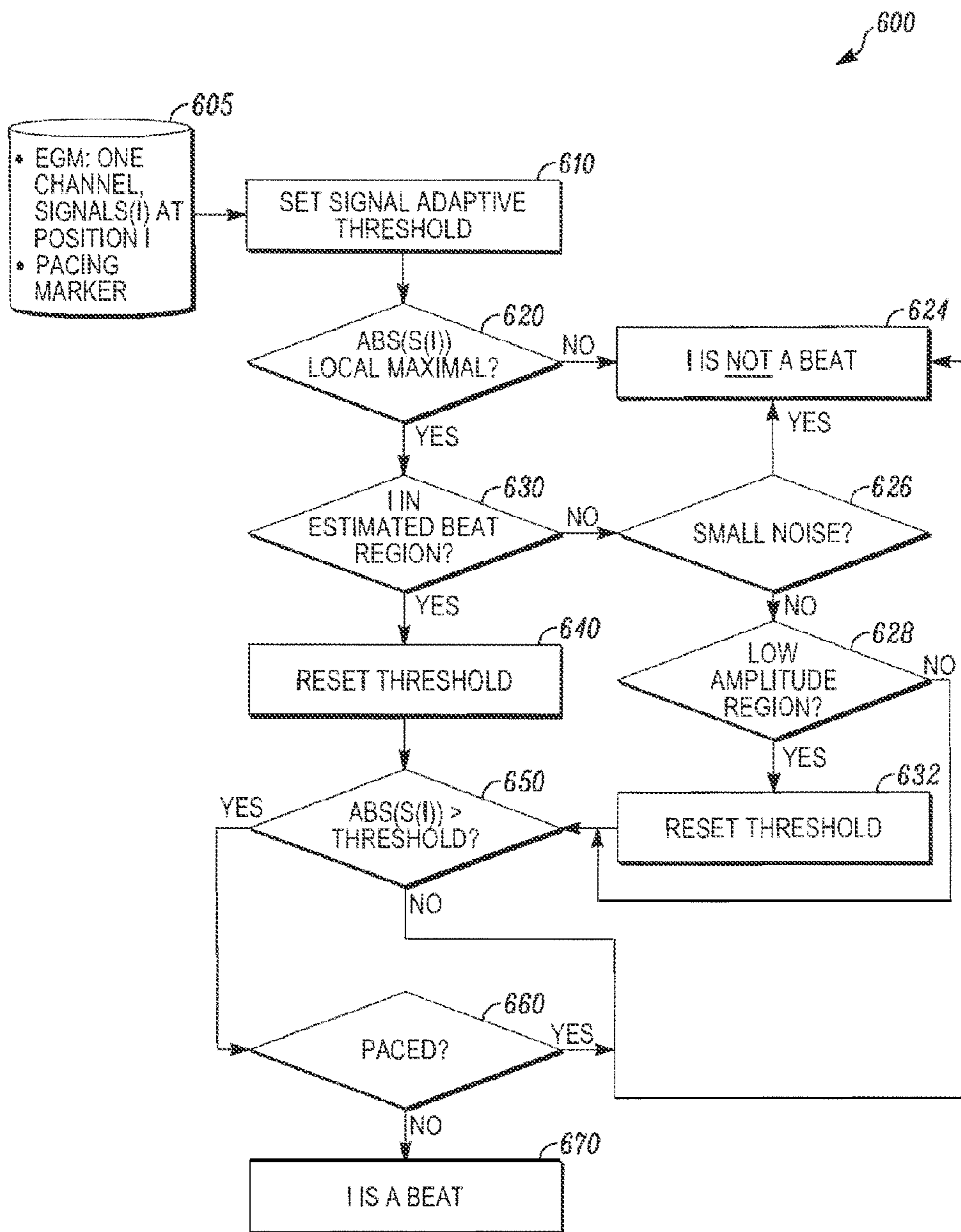


FIG. 6

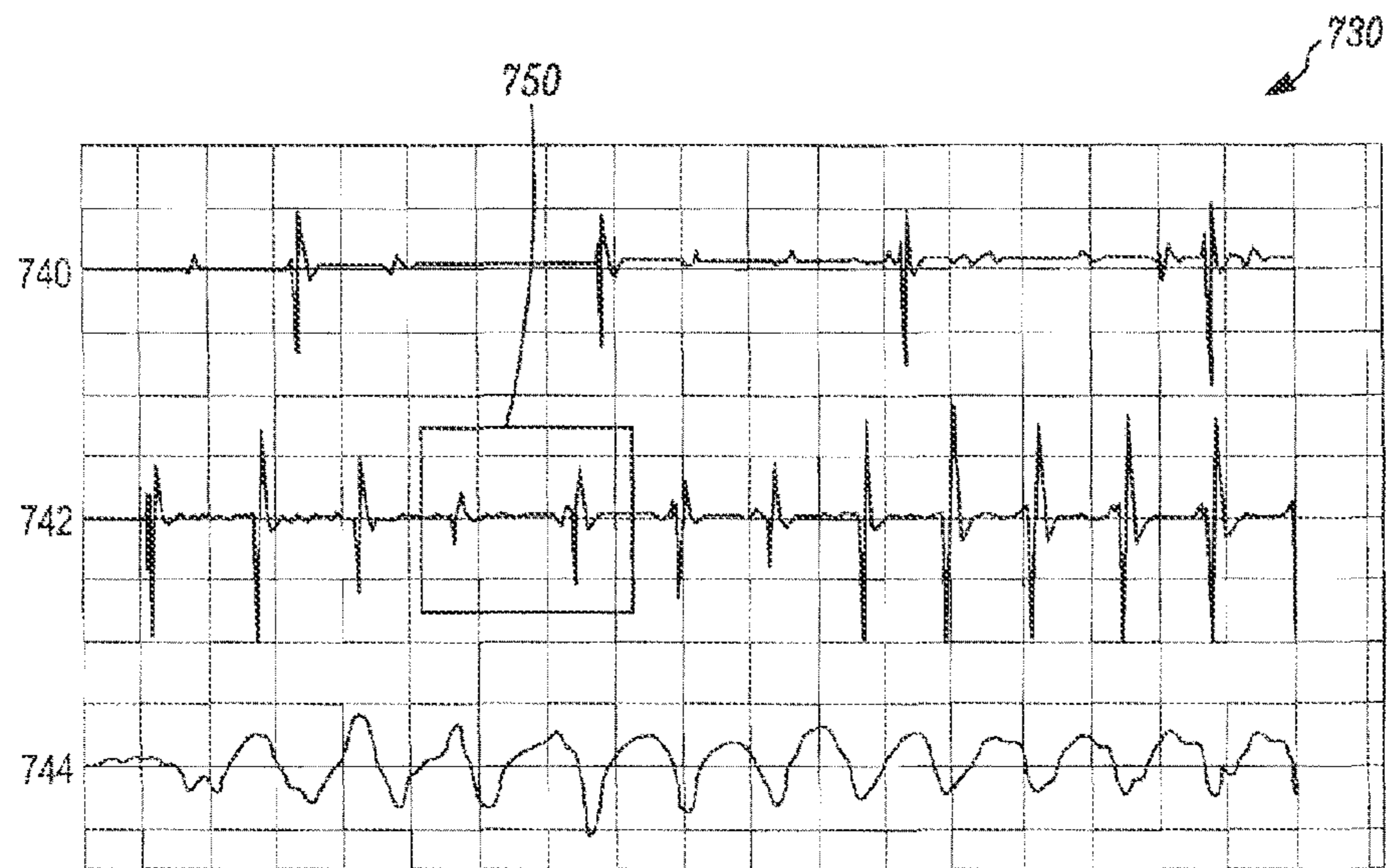
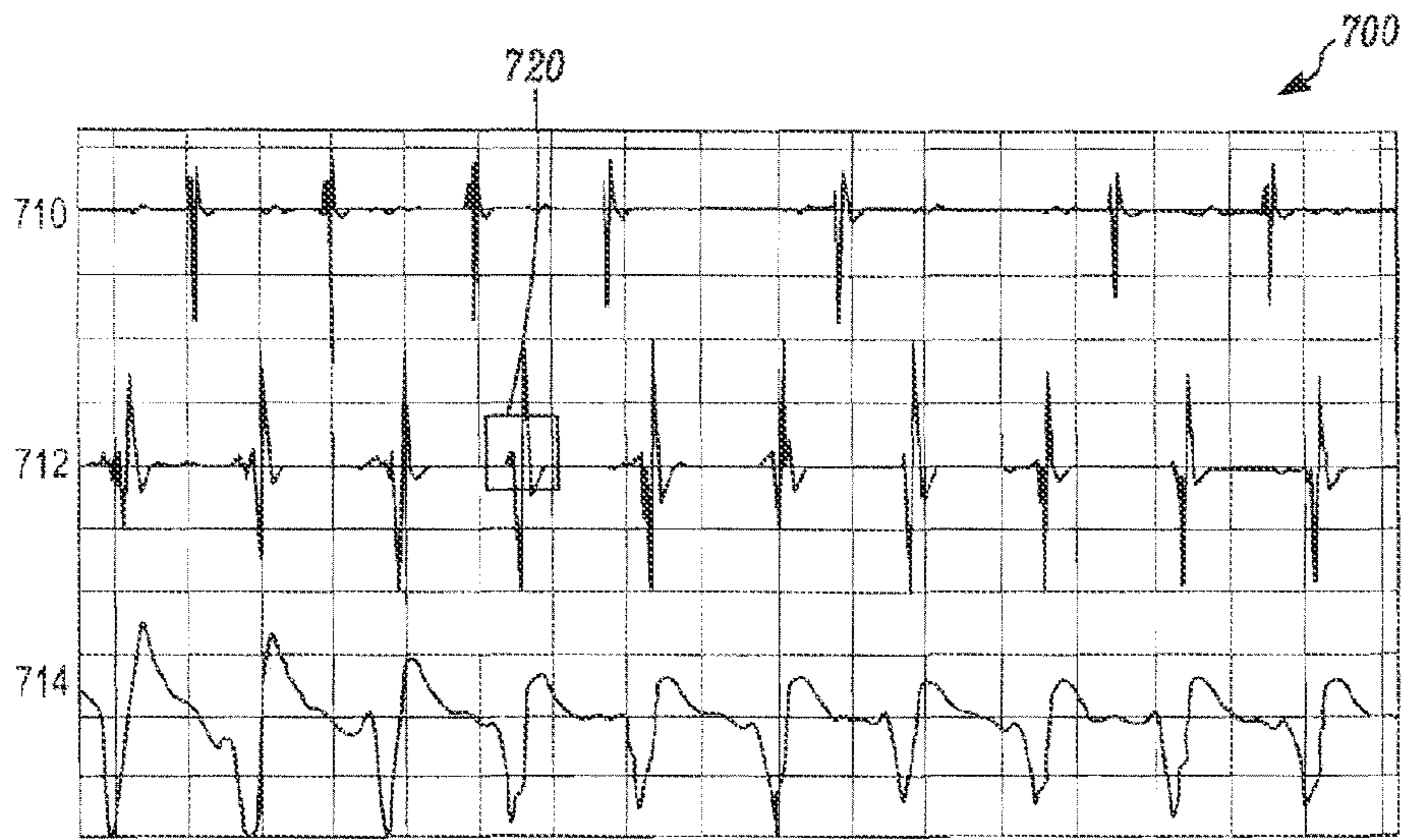


FIG. 7

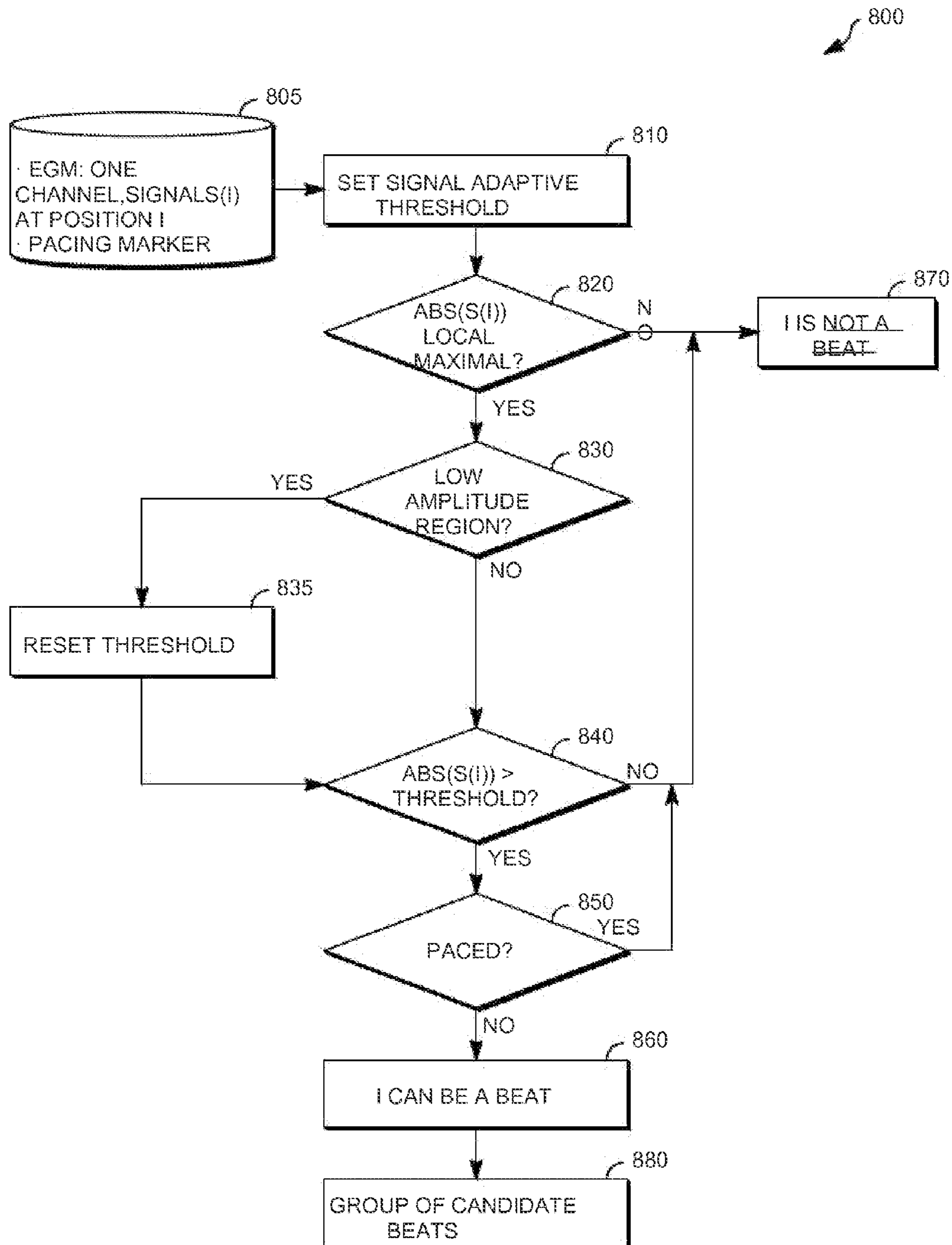


FIG. 8

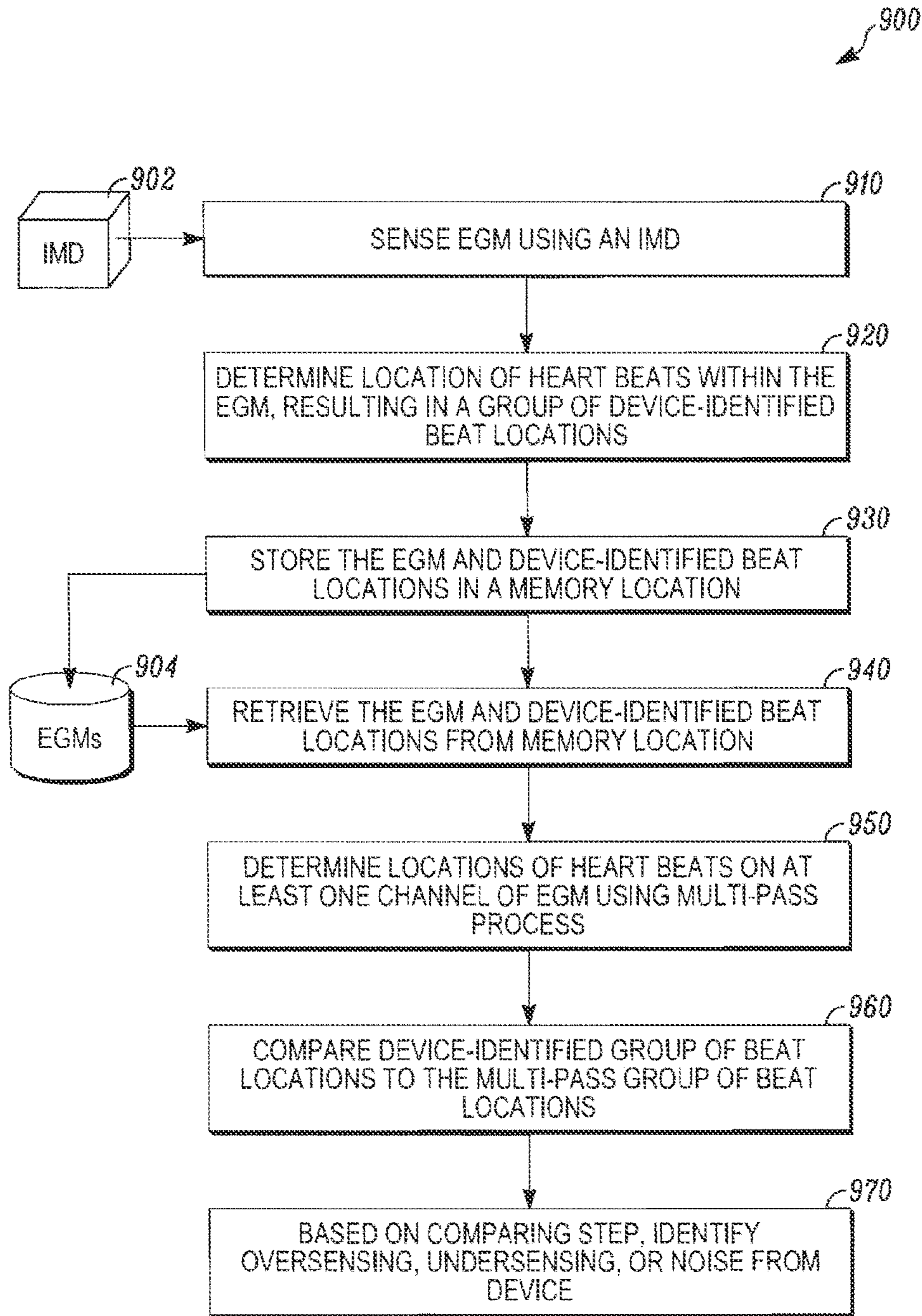
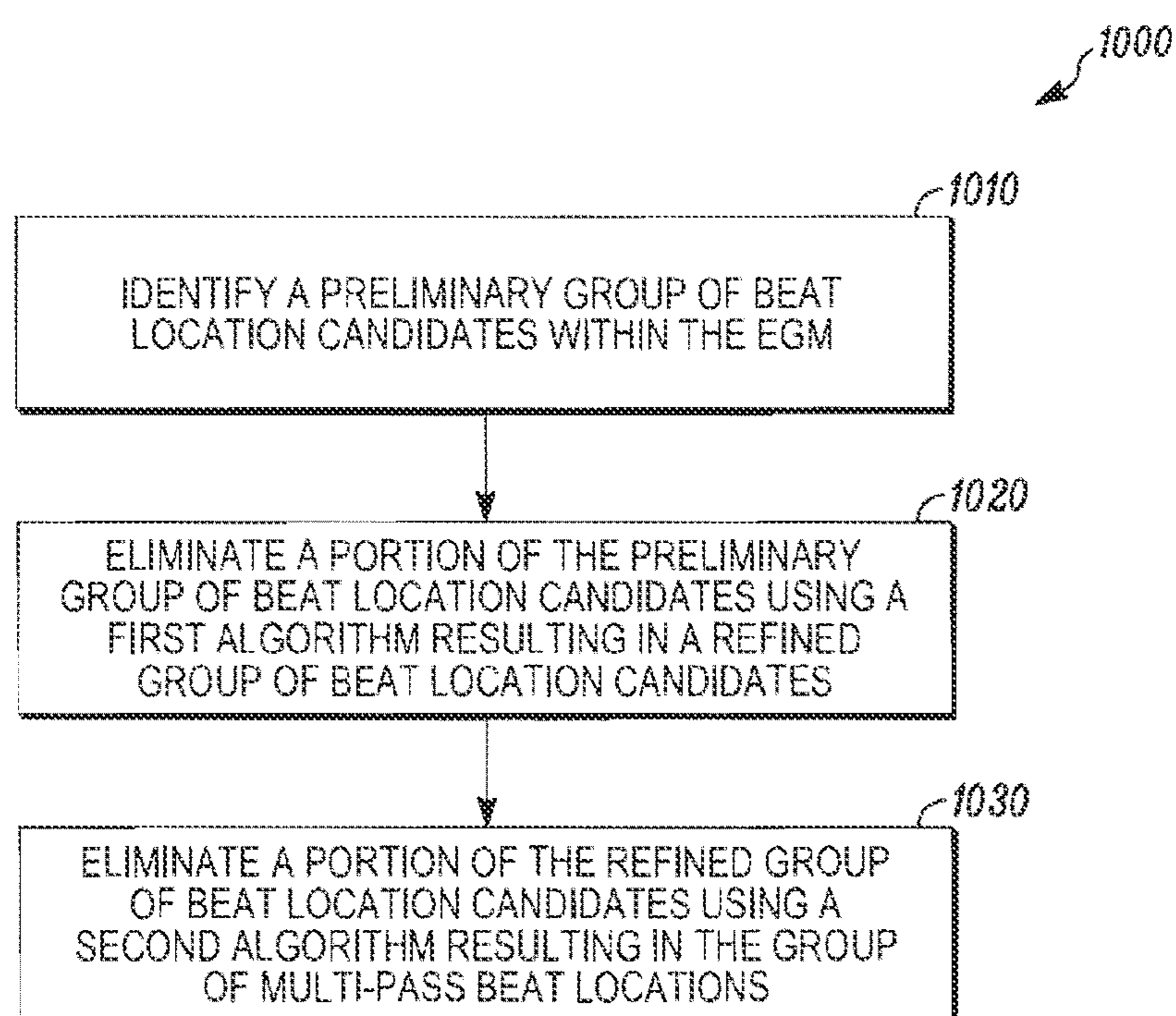


FIG. 9

*FIG. 10*

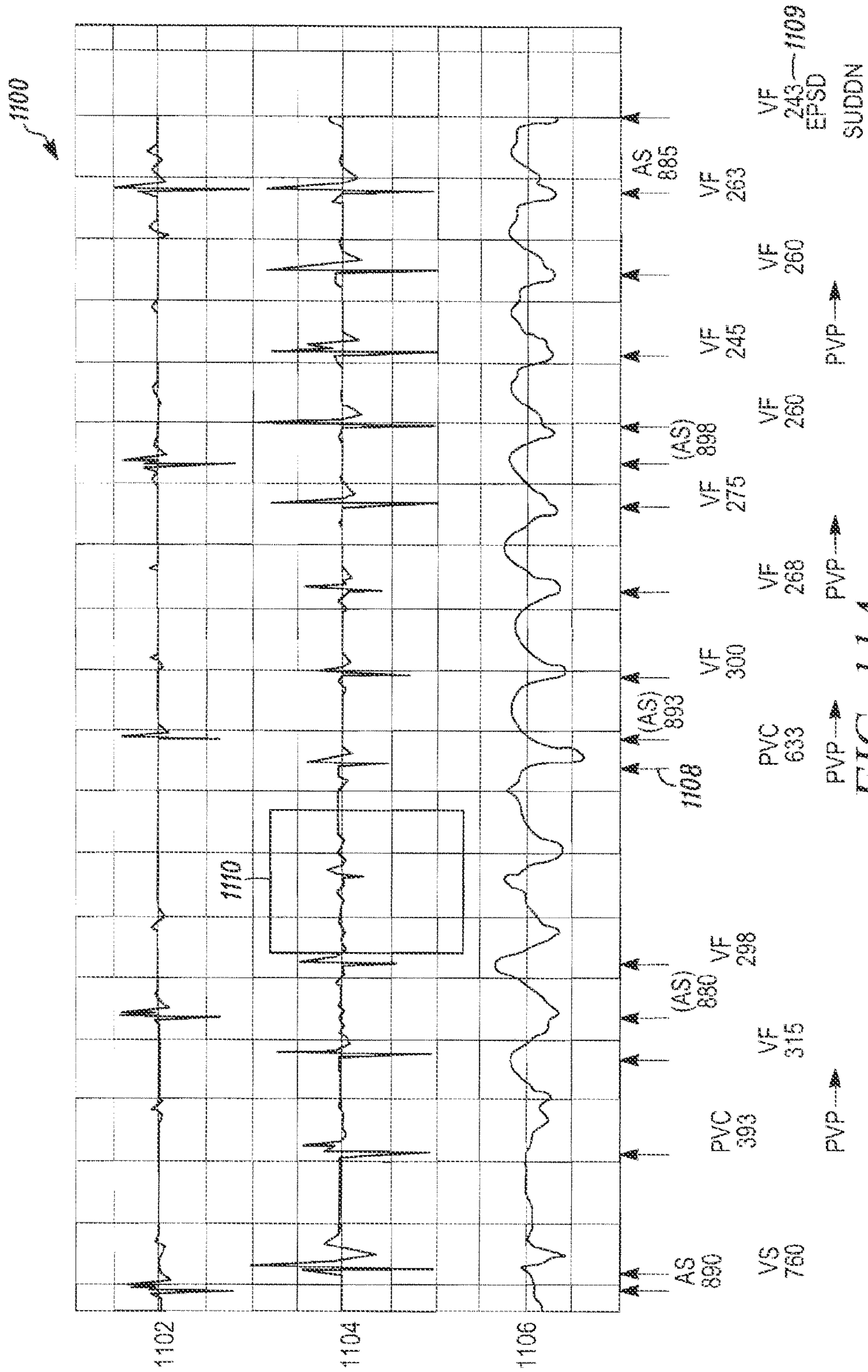


FIG. 11A

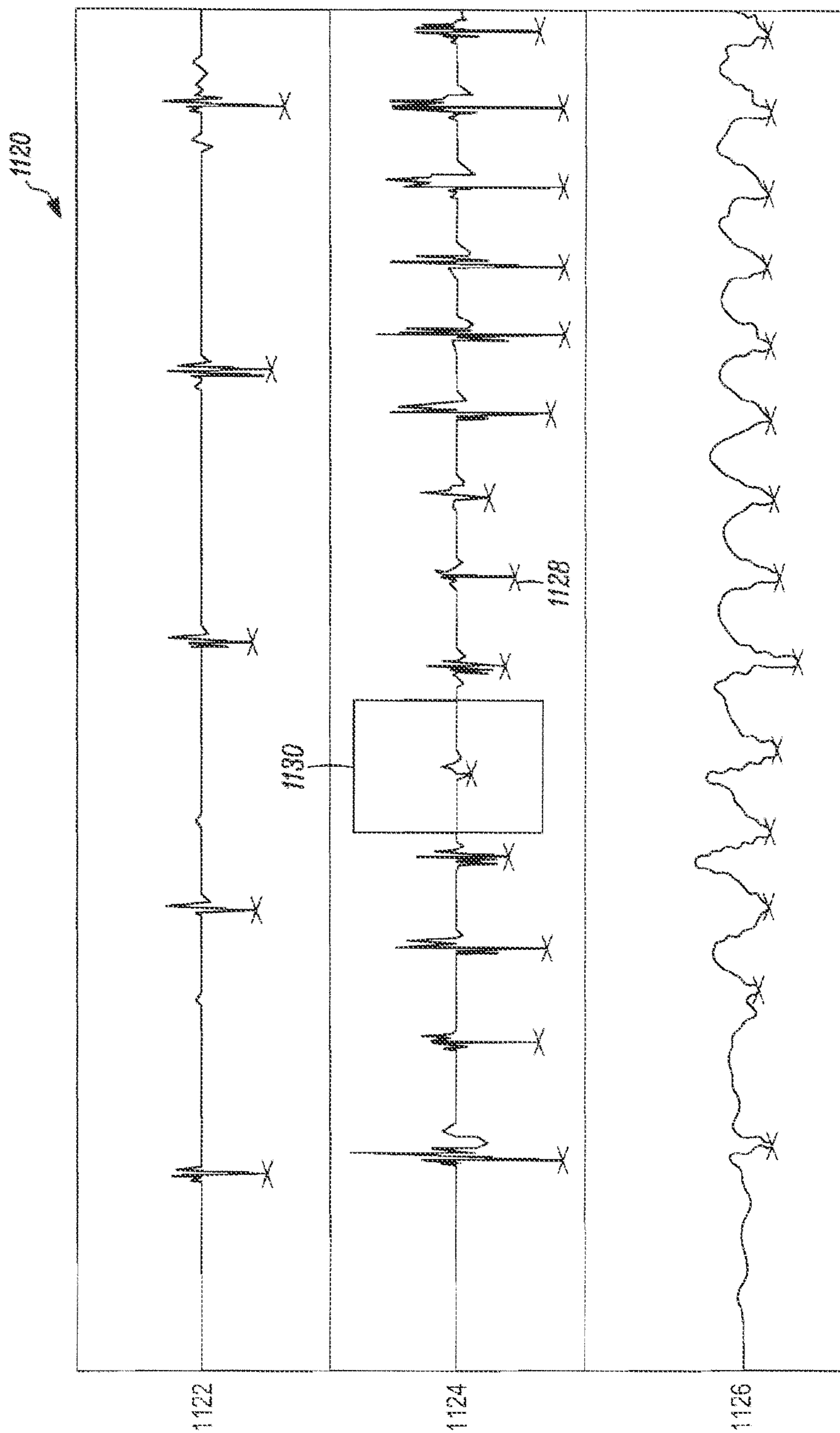


FIG. 11B

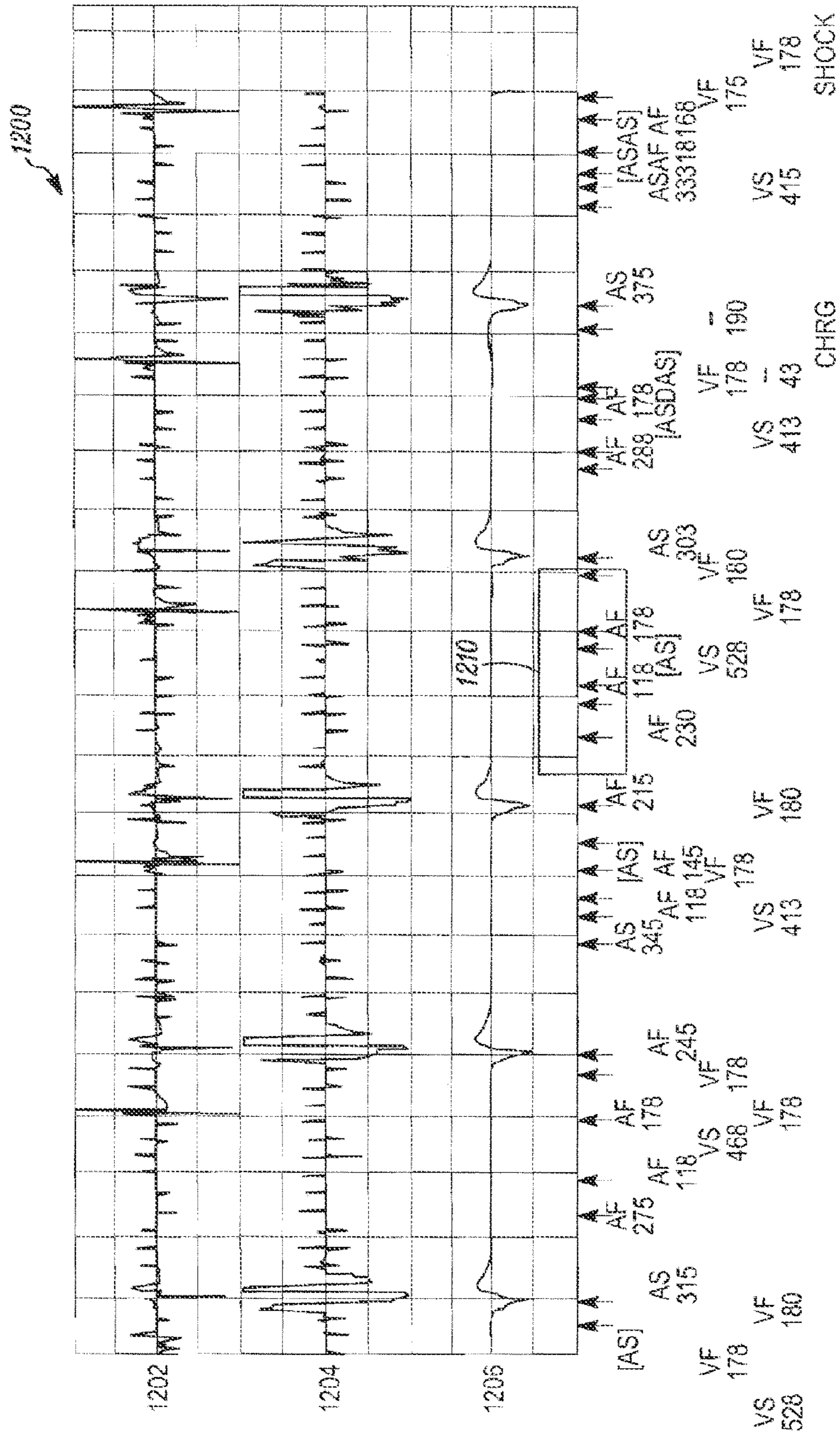


FIG. 12A

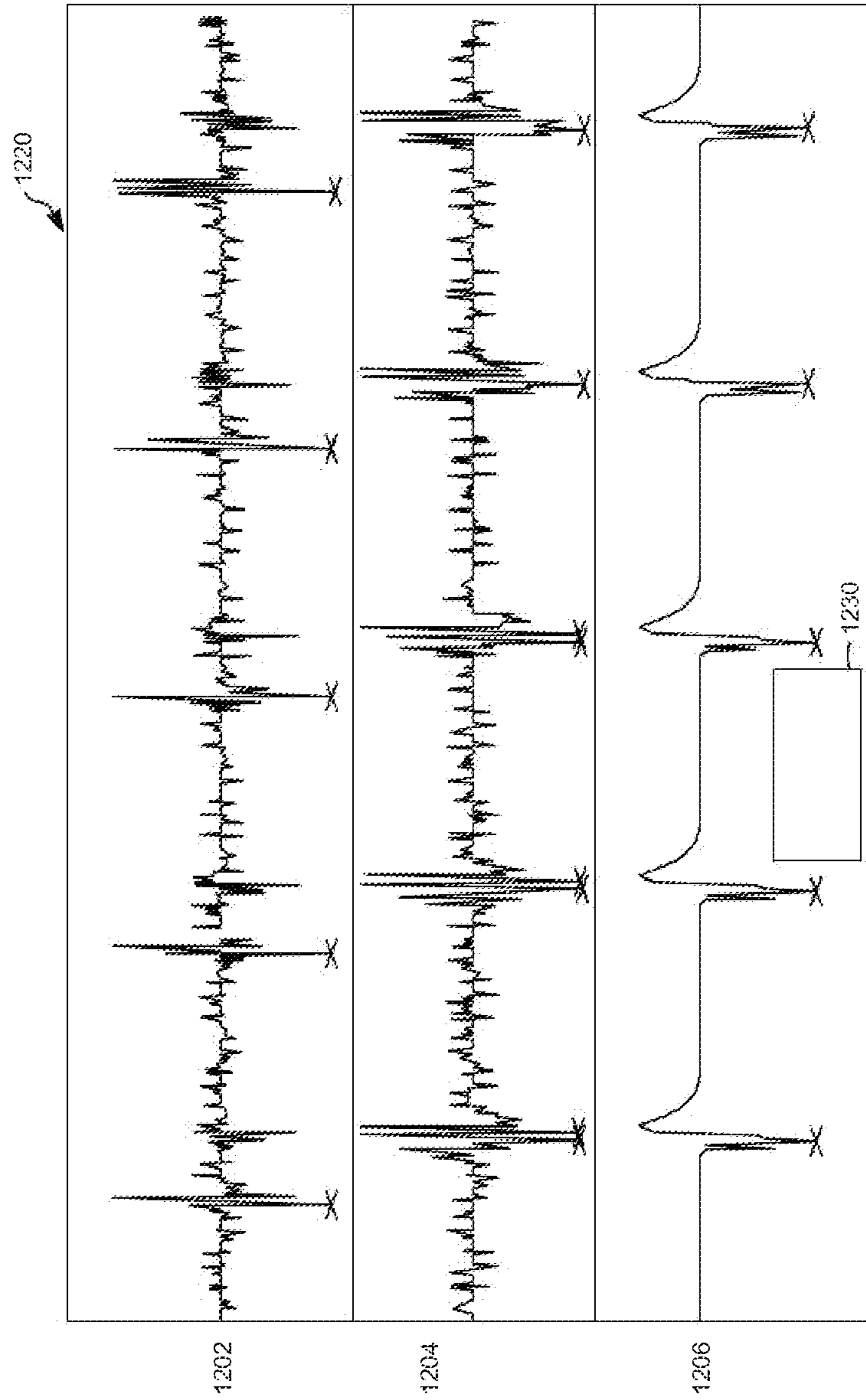


FIG. 12B

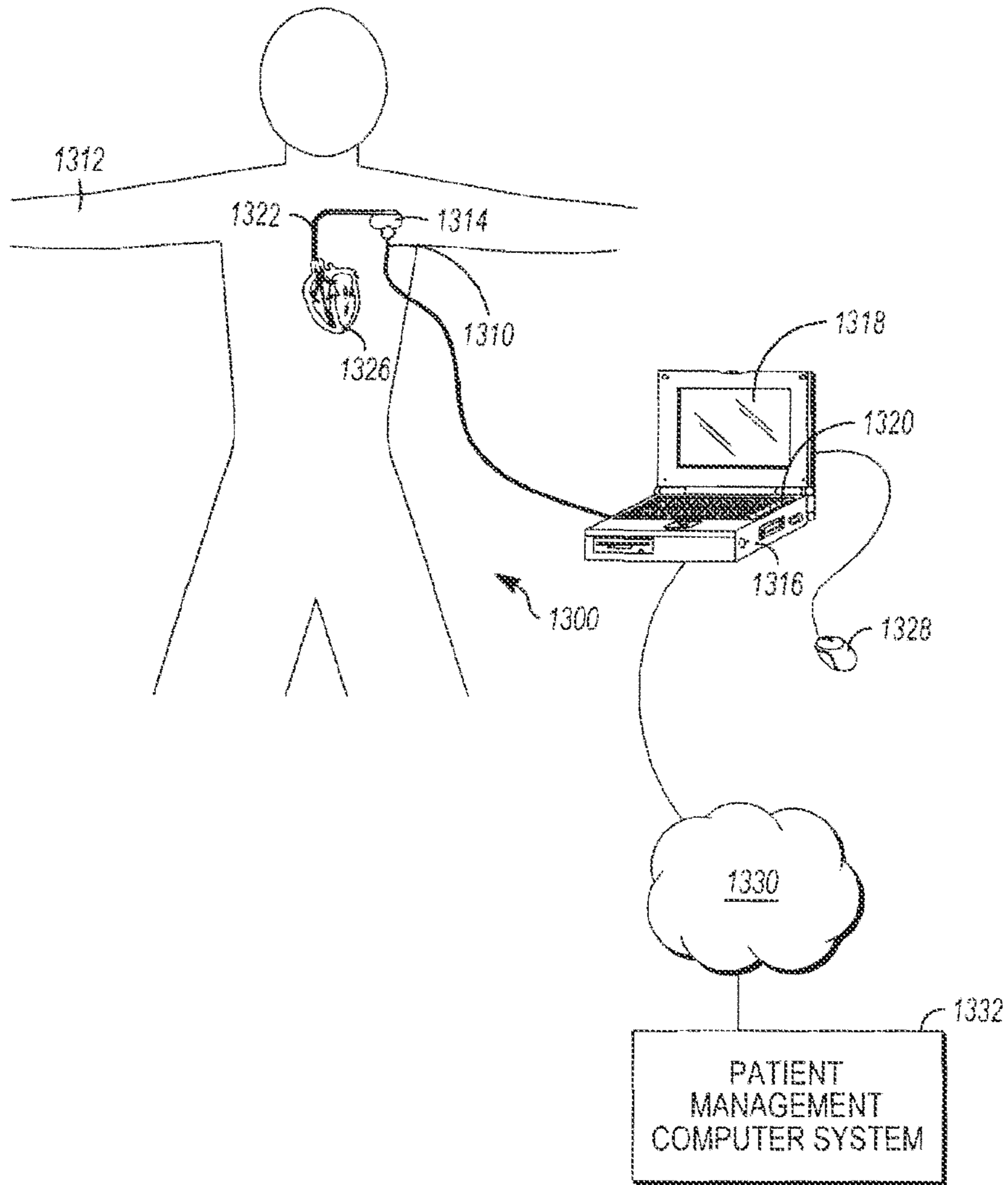


FIG. 13

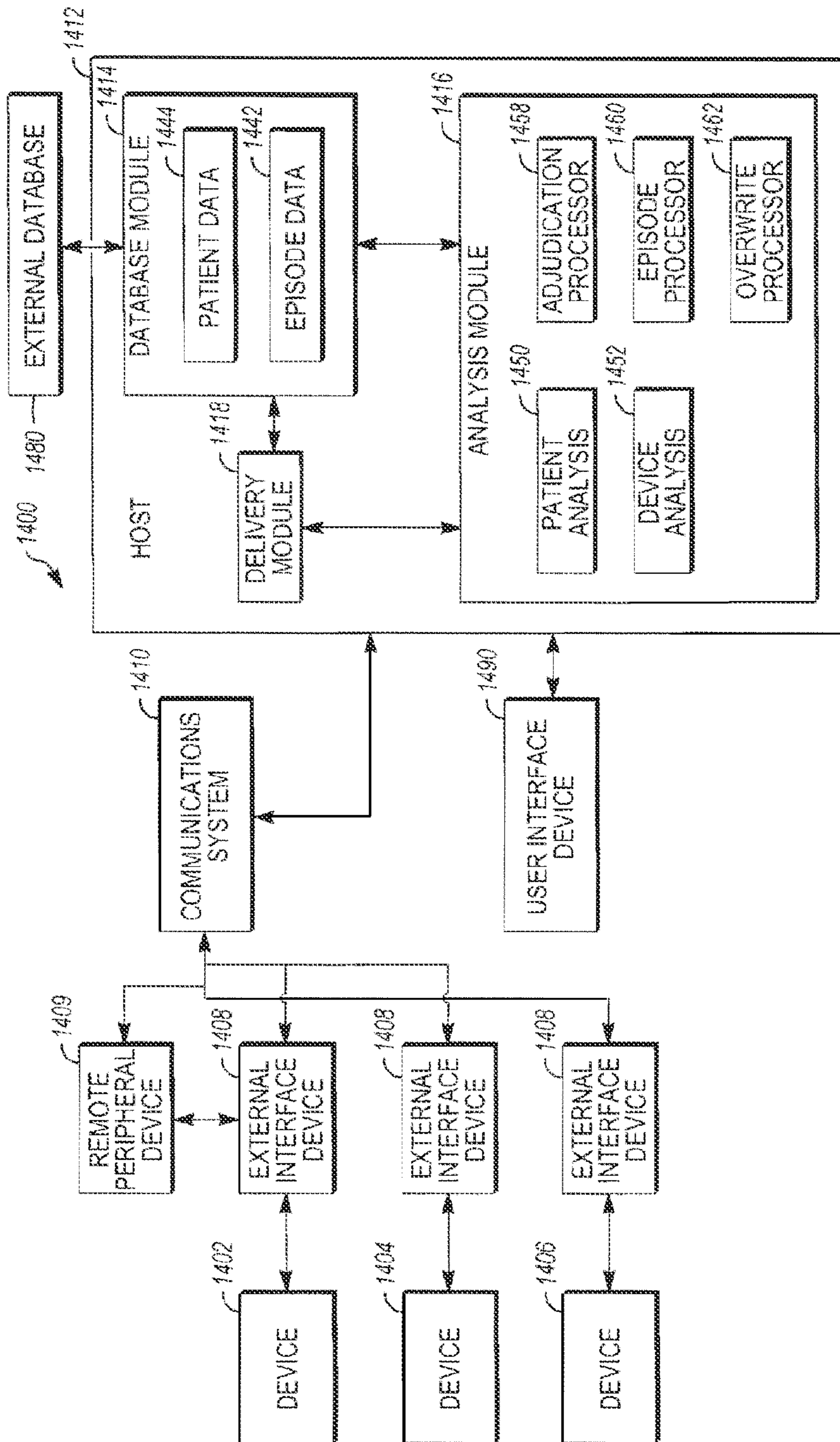


FIG. 14

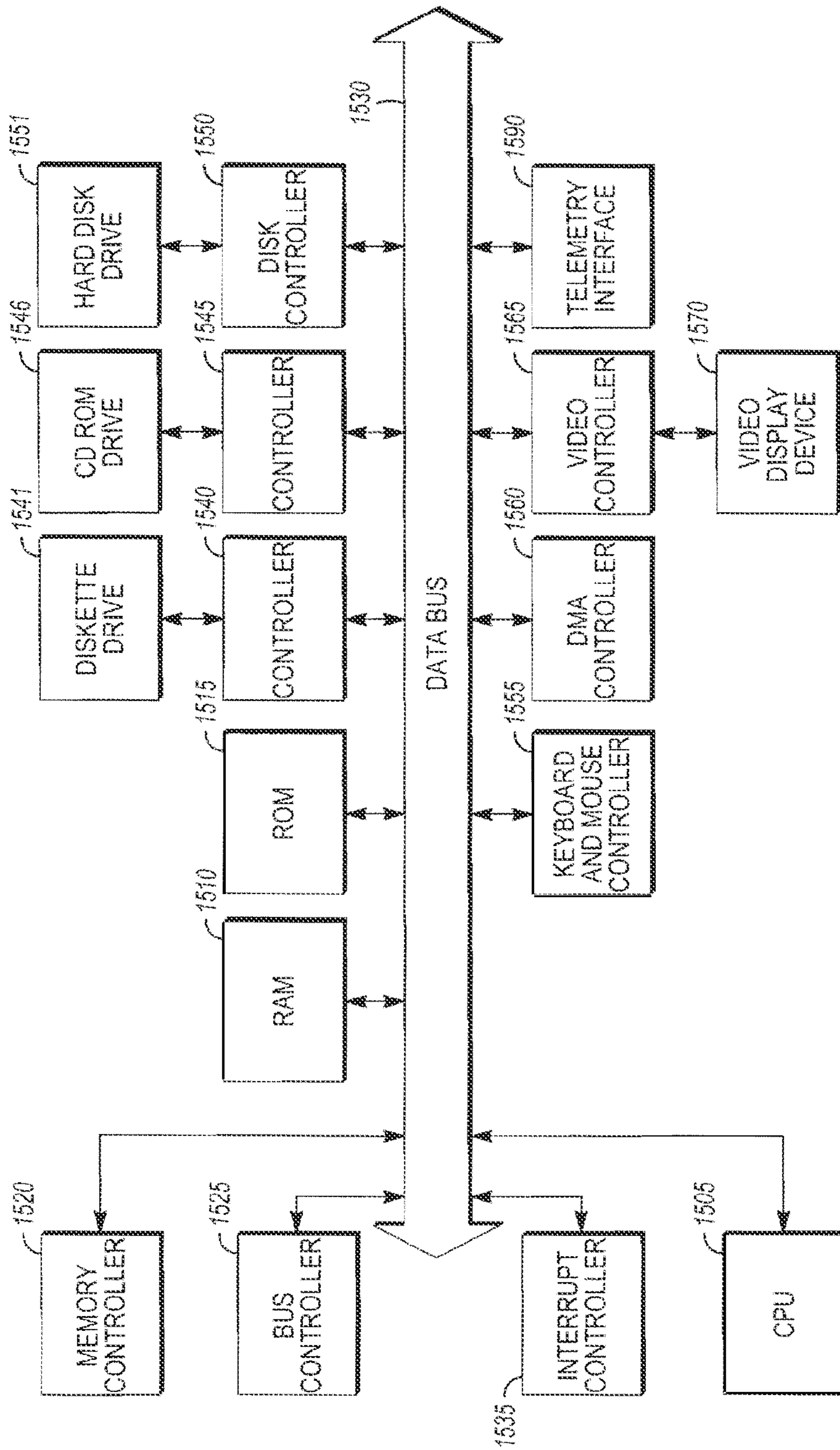


FIG. 15

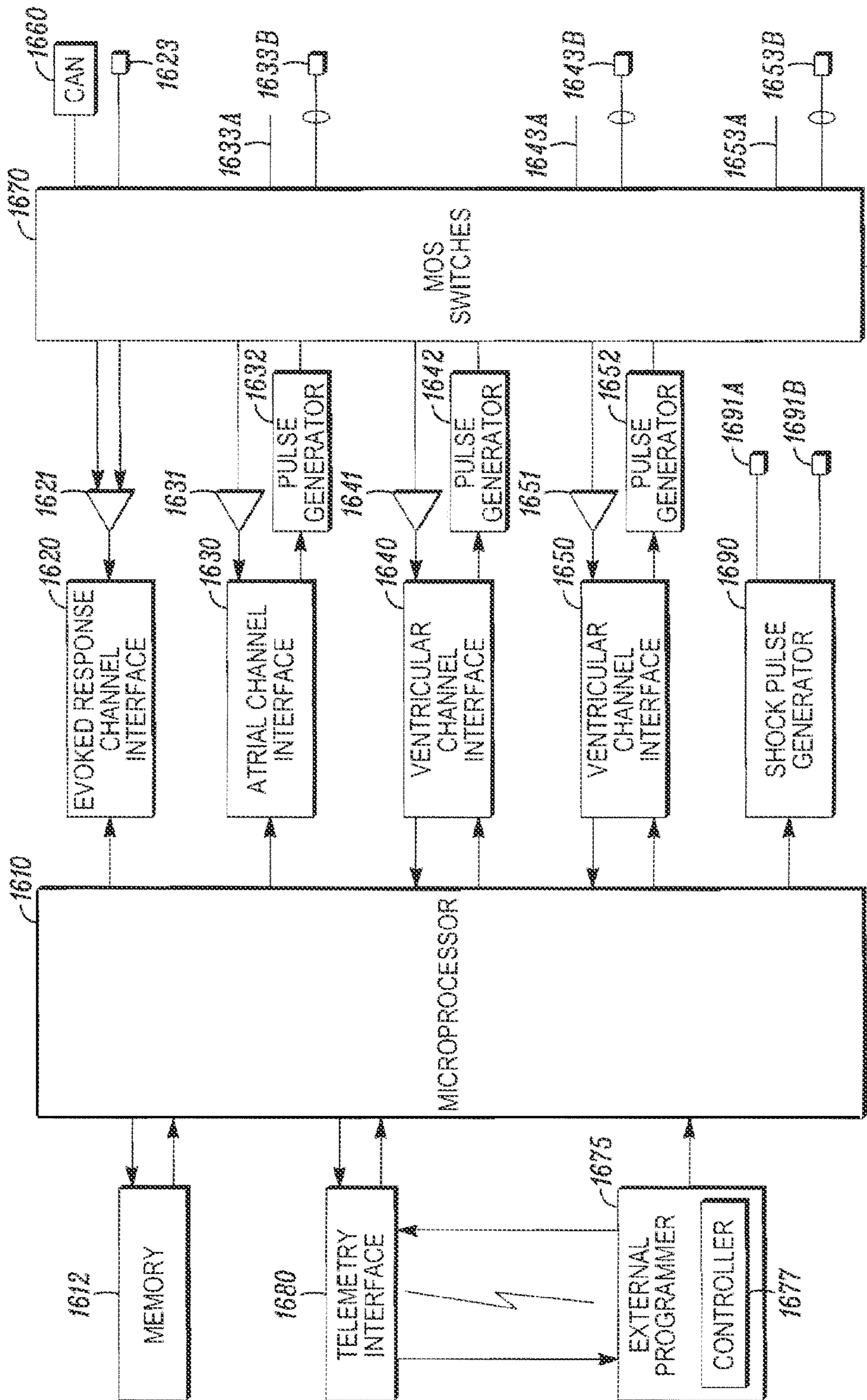


FIG. 16

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**OFF-LINE SENSING METHOD AND ITS
APPLICATIONS IN DETECTING
UNDERSENSING, OVERSENSING, AND
NOISE**

This application claims the benefit of U.S. Provisional Application No. 61/491,451, filed May 31, 2011, the contents of which are herein incorporated by reference.

TECHNICAL FIELD

This disclosure relates generally to systems and methods for analyzing data from a medical device, and more particularly, to medical systems and methods that can be used to analyze cardiac signal data.

SUMMARY OF THE INVENTION

Embodiments of the invention are related to medical systems and methods that can be used to analyze and collect information from implanted medical devices, amongst other things.

In one embodiment, a method for performing independent, off-line evaluation of event sensing for collected electrograms includes the steps of sensing an electrogram using an implantable medical device (IMD); the IMD determining locations of heart beats within the electrogram, resulting in a group of device-identified beat locations for the electrogram; and storing the electrogram and device-identified beat locations in a memory location. The method also includes the steps of retrieving the electrogram and device-identified beat locations from the memory location; and, after retrieving the electrogram from the memory location, determining locations of heart beats on at least one channel of the electrogram using a multi-pass process, resulting in a group of multi-pass beat locations. The multi-pass process includes the steps of identifying a preliminary group of beat location candidates within the electrogram, eliminating a portion of the preliminary group of beat location candidates using a first algorithm resulting in a refined group of beat location candidates, and eliminating a portion of the refined group of beat location candidates using a second algorithm resulting in the group of multi-pass beat locations; and comparing the device-identified group of beat locations to the multi-pass group of beat locations identified using the multi-pass method. Based on the comparison oversensing of beats, undersensing of beats, or noise from the device can be identified.

In another embodiment, a method for performing and evaluating independent, off-line event sensing for collected electrograms includes the steps of sensing an electrogram using an implantable medical device (IMD); determining locations of heart beats within the electrogram, resulting in a group of device-identified beat locations for the electrogram; storing the electrogram and device-identified beat locations in a memory location; and retrieving the electrogram and device-identified beat locations from the memory location. After the electrogram is retrieved from the memory location, locations of heart beats on at least a first channel of the electrogram are determined using a multi-pass process, resulting in a group of multi-pass beat locations. The multi-pass process includes the steps of identifying a preliminary group of beat location candidates within the first channel of the electrogram; eliminating a portion of the preliminary group of beat location candidates using a first algorithm resulting in a refined group of beat location candidates, wherein the first algorithm comprises comparing the amplitude of each of the preliminary beat location candidates with

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a first signal adaptive threshold; and eliminating a portion of the refined group of beat location candidates using a second algorithm resulting in the group of multi-pass beat location candidates, wherein the second algorithm comprises comparing the amplitude of each of the preliminary beat location candidates with a second signal adaptive threshold. Finally, the device-identified group of beat locations are compared to the multi-pass group of beat locations identified using the multi-pass method. The comparison may be used to identify oversensing of beats, undersensing of beats, or noise from the device.

In yet another embodiment, a system is provided that performs independent, off-line evaluation of event sensing for collected electrograms. The system includes an implantable medical device (IMD) configured to collect one or more electrograms from a patient and determine locations of heart beats within the one or more electrograms. The IMD comprises a memory for storing patient data, where the patient data includes the one or more electrograms and one or more groups of device-identified beat locations for the electrograms. The system further includes an external computing device configured to retrieve patient data comprising the one or more electrograms and the one or more groups of device-identified beat locations for the electrograms. The external computing device includes a database module comprising memory for storing patient data including one or more electrograms and one or more groups of device-identified beat locations for the electrograms. The external computing device further includes an analysis module configured to determine locations of heart beats on at least one channel of the electrogram using a multi-pass process, resulting in a group of multi-pass beat locations.

The disclosed methods and systems can be used to detect undersensing, oversensing, and noise and to provide alerts and programming recommendations. The methods and systems may also be used to reduce inappropriate shocks.

This summary is an overview of some of the teachings of the present application and is not intended to be an exclusive or exhaustive treatment of the present subject matter. Further details are found in the detailed description and appended claims. Other aspects will be apparent to persons skilled in the art upon reading and understanding the following detailed description and viewing the drawings that form a part thereof, each of which is not to be taken in a limiting sense. The scope of the present invention is defined by the appended claims and their legal equivalents.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be more completely understood in connection with the following drawings, in which:

FIG. 1 is an illustration of portions of a system that use an implantable medical device.

FIG. 2 is an electrogram showing an example of far-field sensing on the right atrial (RA) channel.

FIG. 3 is a flowchart showing an off-line method for analyzing cardiac electrogram data.

FIG. 4 is a flowchart of an embodiment of a multi-pass method.

FIG. 5 is a flowchart of an alternative embodiment of a multi-pass method for use with atrial and ventricular beats.

FIG. 6 is a flowchart showing one embodiment of beat detection on one channel of an electrogram.

FIG. 7 shows an electrogram where an example estimated beat region is labeled (above) and an electrogram where an example low amplitude region is labeled (below).

FIG. 8 is a flowchart showing another embodiment of beat detection on one channel of an electrogram.

FIG. 9 is a flowchart showing one embodiment of an independent, off-line evaluation of event sensing for collected electrograms.

FIG. 10 is a flowchart of an alternative embodiment of a multi-pass method.

FIG. 11A shows an electrogram with data sensed by a CRM device. FIG. 11B shows an electrogram using the data from FIG. 11A that is further analyzed to show where beats are detected using an off-line multi-pass algorithm to reduce undersensing in accordance with an embodiment of the invention.

FIG. 12A shows an electrogram with data sensed by a CRM device. FIG. 12B shows an electrogram using the data from FIG. 12A that is further analyzed to show where beats are detected using an off-line multi-pass algorithm to reduce oversensing in accordance with an embodiment of the invention.

FIG. 13 is a schematic diagram of an exemplary implementation of a cardiac rhythm management (CRM) system, including an implanted CRM device, an external interface device, and a patient management computer system, consistent with at least one embodiment of the invention.

FIG. 14 is a schematic illustration of a patient management system consistent with at least one embodiment of the invention.

FIG. 15 is a schematic diagram of an implementation of the components of an external interface device such as a programmer, in accordance with various embodiments.

FIG. 16 is a block diagram of an implantable medical device.

While the invention is susceptible to various modifications and alternative forms, specifics thereof have been shown by way of example and drawings, and will be described in detail. It should be understood, however, that the invention is not limited to the particular embodiments described. On the contrary, the intention is to cover modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

DETAILED DESCRIPTION

This disclosure relates generally to medical data-generating devices and, more particularly, to systems and methods for analyzing information from such medical devices. In particular, this disclosure relates to systems and methods for performing analysis on cardiac signals to detect oversensing, undersensing, and noise by a particular data-generating device or analysis method. Methods of detecting heart beats on at least one channel are used to output a group of candidate beats. The candidate beats can then be used in combination with far-field sensing removal techniques described herein, so that there is more confidence that the remaining beats are actual heart beats. Far-field sensing is sensing of signals from distant ventricular activity that is detected by the atrial lead.

The heart pumps oxygen-rich blood through the arteries to tissues, including organs, muscles, and nerves. The cardiac conduction system includes specialized cardiac muscle cells in the walls of the heart that send signals to the heart muscle causing it to contract. The main parts of the cardiac conduction system are the SA node, AV node, bundle of His, bundle branches, and Purkinje fibers. The normal pattern of a heart beat begins when electrical signals are conducted to the top chambers of the heart, the left atrium and right atrium. The SA node starts the process by causing the atrial muscles to contract, pushing blood into the two lower chambers, the left

ventricle and right ventricle. Then, the electrical signal travels to the AV node, through the bundle of His, down the bundle branches, and through the Purkinje fibers, causes the ventricles to contract, pushing blood to the heart and the rest of the body. This signal creates an electrical current that can be seen on an electrogram or electrocardiogram.

Methods for performing independent, off-line evaluation of event sensing for collected electrograms are used, which utilize electrogram (EGM) data from an implantable medical device (IMD). The IMD determines locations of heart beats within the EGM data, resulting in a group of device-identified beat locations. These may also be known as device markers. The EGM data and device-identified beat locations are stored in a memory location. Next, a computer or other computing device such as a programmer is used to retrieve the EGM data and device-identified beat locations from the memory location. The computing device determines the locations of heart beats on at least one channel of EGM data using a multi-pass process. The group of beat locations determined using this multi-pass process is referred to as the multi-pass group of beat locations. The computing device analyzes and compares the device-identified group of beat locations with the multi-pass group of beat locations. Based on the comparison, the presence of oversensing, undersensing, or noise can potentially be confirmed in the device-identified beat locations.

Cardiac signals can be in the form of EGMs, heart sound signals, impedance signals, and pressure signals. Data-generating devices include IMDs, while in some embodiments the data generating devices are external or subcutaneous. In some embodiments, the information gathered includes an intracardiac EGM.

IMDs may be a part of a cardiac rhythm management system (CRM system) that includes an implantable cardiac rhythm management device (CRM device), an external interface device and a patient management computer system. An implanted cardiac rhythm management (CRM) device can be used to provide pacing therapy to a patient with sinus node dysfunction, in one example, where the heart fails to properly initiate depolarization waves, or an atrio-ventricular conduction disturbance, where the conduction of depolarization waves through the heart tissue is impaired, or to support and treat patients with many different types of cardiac issues. Examples of implantable medical devices that may be used to gather data include implantable pacemakers, implantable cardioverter defibrillators (ICDs), and devices that include a combination of pacing and defibrillation including cardiac resynchronization therapy.

A cardiac signal is a record of the heart's activity. An EGM is a recording of cardiac electrical activity represented by the voltage signal produced by one or more sensing electrodes in a cardiac device. EGM signals can be digitized and recorded by a cardiac device and then either transmitted via a telemetry link to an external programmer or stored for later transmission. The patient's cardiac activity can thus be observed in real-time or over a selected historical period for diagnostic purposes offline at a later time.

The science of morphology deals with interpretation of the shape characteristics of the cardiac signals, such as EGM signals, where such shape characteristics include amplitude, width and contour. The morphology of a cardiac waveform can be used to discriminate between different types of cardiac arrhythmias and other cardiac events, and morphology information can be very useful to clinicians treating the patient.

IMD System

FIG. 1 is an illustration of portions of a system that uses an implanted medical device (IMD) 110. Other types of cardiac rhythm management (CRM) devices may also be used includ-

ing external medical devices. Examples of IMDs **110** include, without limitation, a pacemaker, a defibrillator, a cardiac resynchronization therapy (CRT) device, or a combination of such devices. The system also typically includes an IMD programmer or other external device **170** that communicates wireless signals **190** with the IMD **110**, such as by using radio frequency (RF) or other telemetry signals.

The IMD **110** is coupled by one or more leads **108A-C** to the heart **105**. Cardiac leads **108A-C** include a proximal end that is coupled to IMD **110** and a distal end, coupled by an electrode or electrodes to one or more portions of a heart **105**. The electrodes typically deliver cardioversion, defibrillation, pacing, or resynchronization therapy, or combinations thereof to at least one chamber of the heart **105**. The electrodes may be electrically coupled to sense amplifiers to sense electrical cardiac signals.

The heart **105** includes a right atrium **100A**, a left atrium **100B**, a right ventricle **105A**, a left ventricle **105B**, and a coronary sinus extending from right atrium **100A**. The atrial lead **108A** includes electrodes (electrical contacts, such as ring electrode **125** and tip electrode **130**) disposed in the right atrium **100A** of heart **105** for sensing signals, or delivering pacing therapy, or both, to the right atrium **100A**.

The ventricular lead **108B** includes one or more electrodes, such as tip electrode **135** and ring electrode **140**, for sensing signals, delivering pacing therapy, or both sensing signals and delivering pacing therapy. The lead **108B** optionally also includes additional electrodes, such as for delivering atrial cardioversion, atrial defibrillation, ventricular cardioversion, ventricular defibrillation, or combinations thereof to the heart **105**. Such electrodes typically have larger surface areas than pacing electrodes in order to handle the larger energies involved in defibrillation. The lead **108B** optionally provides resynchronization therapy to the heart **105**.

The IMD **110** may include a third cardiac lead **108C** attached to the IMD **110** through the header **155**. The third cardiac lead **108C** includes ring electrodes **160**, **165** placed in a coronary vein lying epicardially on the left ventricle (LV) **105B** via the coronary vein **120**.

The lead **108B** may include a first defibrillation coil electrode **175** located proximal to tip and ring electrodes **135**, **140** for placement in a right ventricle (RV), and a second defibrillation coil electrode **180** located proximal to the first defibrillation coil **175**, tip electrode **135**, and ring electrode **140** for placement in the superior vena cava (SVC). In some examples, high-energy shock therapy is delivered from the first or RV coil **175** to the second or SVC coil **180**. In some examples, the SVC coil **180** is electrically tied to an electrode formed on the hermetically-sealed IMD can **150**. This improves defibrillation by delivering current from the RV coil **175** more uniformly over the ventricular myocardium. In some examples, the therapy is delivered from the RV coil **175** only to the electrode formed on the IMD can **150**.

Other forms of electrodes include meshes and patches which may be applied to portions of heart **105** or which may be implanted in other areas of the body to help “steer” electrical currents produced by IMD **110**. The present methods and systems will work in a variety of configurations and with a variety of electrical contacts or “electrodes.” Sensing among different sets of electrodes often provides directional information regarding the propagation of cardiac signals and is often referred to as sensing among different vectors. For example, in a single chamber ICD, sensing from a right ventricular tip electrode **135** to a right ventricular ring electrode **140** would be a first vector, and sensing from an RV coil **175** to an electrode on the can **150**, or a header **155**, would be second vector. Various electrode configurations may be used,

as described in co-pending and commonly-assigned U.S. Publication No. 2010/0204745, filed Jan. 26, 2010, the contents of which are herein incorporated by reference.

The electrode configuration used in the systems and methods described herein allow for the collection of EGMs on at least one channel, while multiple channels may be used. In one embodiment, signals from a first and second channel of an EGM are analyzed. When electrodes are implanted in or near an atrium, a signal from an atrial channel is provided. A ventricular EGM signal is recorded with electrodes implanted in or near a ventricle, called a ventricular channel. For example, a ventricular channel or vector may include a tip electrode and ring electrode for the right ventricular channel or ring electrodes for the left ventricular channel. The atrial and ventricular channels are also sometimes referred to as rate channels because they can be used to sense the heart’s depolarization rate. Another channel, known as the shock channel or shock vector, may be used. The shock channel is sensed using electrodes that are also used to delivery high-energy shock therapy. In one example, the shock channel includes an electrode placed at the superior vena cava (SVC). In another example, the shock channel includes an electrode placed in the RV.

Description of Noise, Undersensing, and Oversensing

The sensing of signals by the IMD **110** may be susceptible to noise. The signal noise may be physiologic or non-physiologic in nature. Non-physiologic signal noise may be intracardiac in origin due to a separate electronic device providing electrical therapy. The IMD **110** may sense the therapy. Intracardiac non-physiologic signal noise may also be due to the sensing electrode or lead making electrical contact with an abandoned lead fragment.

Non-physiological noise can also be extracardiac (external to the heart) in origin. The noise may be due to the device itself, such as due to fracture of an IMD lead, a faulty set screw or adapter used for securing an IMD lead, or electronic “chatter” picked up by the IMD lead. Non-physiologic noise sources separate from the IMD include electrocautery during surgery, magnetic resonance imaging, a lithotripsy procedure, or transmissions from electronic surveillance equipment.

Physiologic noise can also be intracardiac or extracardiac in origin. Examples of intracardiac physiologic noise includes a low amplitude R-wave or a prolonged Q-T segment of a sensed cardiac activation signal that complicates identification of a T-wave, and dislodgement of a ventricular lead that complicates the sensing and identifying of a P-wave or causes double-counting of an R-wave.

Extracardiac physiologic noise includes oversensing of abdominal or diaphragmatic myopotentials (DMPs). DMPs are electrical activation signals related to contractions of the diaphragm. DMPs may be sensed by the IMD due to the position of implanted leads used to sense cardiac depolarization or due to failure of the insulation of the implanted leads. In the absence of a lead abnormality, oversensing of noise that leads to inappropriate delivery of cardioverting or defibrillating shock therapy is most commonly due to DMPs. The DMPs are incorrectly identified by an IMD as ventricular tachyarrhythmia, such as ventricular fibrillation (VF) or VT for example. Consequently, accurately discriminating DMPs from actual arrhythmias reduces delivery of inappropriate shocks from devices with cardioverter/defibrillator capability.

Undersensing is an intrinsic depolarization that is present but not seen or sensed by the device. In a pacemaker, undersensing may be caused by inappropriately programmed sensitivity, lead dislodgment, lead failure (i.e. insulation break,

conductor fracture), lead maturation, or change in the native signal. Oversensing is the sensing of an inappropriate signal, which can be either physiologic or non-physiological. Where oversensing occurs, the channel signal may not correspond with the electrogram pattern of the other channel from the same chamber. Oversensing may be caused by lead insulation failure, lead fracture, or a lead connection problem.

Other factors are also of concern with cardiac devices. Generally, the larger the detected signal, the better. In certain devices, if the signal passed through the right ventricular (RV) lead (R wave) is too small, then a pacemaker or other IMD may not sense intrinsic rhythm and begin pacing inappropriately, creating a risk for arrhythmia. Furthermore, if the R wave is too small and a particular device is programmed to account for small signals, there is a possibility that the lead will detect a signal that is not ventricular activity and incorrectly not pace the ventricle when the patient is potentially asystolic. In the case of the right atrial (RA) lead, both the size of the signal sensed on the RA lead (P wave) and the presence of distant but detectable ventricular activity are significant. The distant ventricular activity that is still detected by the atrial lead is known as far-field sensing. The EGM **200** of FIG. **2** shows an example far-field signal **210** on the right atrial (RA) channel **220**. The ventricular channel **230** and shock channel **240** are also shown on the EGM **200**. If far-field activity is too large relative to an atrial signal, an IMD may sense both the far-field and the atrial signal and determine that both are atrial signals, counting two beats instead of one. The methods described herein seek to detect and remove far-field signals to improve the accuracy of beat detection.

Representative Electrograms

An implantable cardiac device configured with one or more sensing channels and associated circuitry for recording and storing electrograms is programmed to generate representative electrograms with respect to time and/or with respect to heart rate. A representative electrogram may be a single electrogram recorded during a specified time or when the heart rate is within a specified range or may be an average of electrograms recorded during a discrete time interval. Averages may be computed as moving averages of electrograms recorded either continuously or periodically during a discrete time interval or when the heart rate is within a specified range. The representative electrograms may reflect either intrinsic or paced cardiac electrical activity, or separate representative electrograms may be derived from intrinsic and paced beats. A set of representative electrograms may be downloaded to an external programmer (or other external device), which can then graphically display the downloaded representative electrograms as an aggregate indexed with respect to time or heart rate. In one embodiment, rather than being reviewed real-time, electrograms may alternatively be downloaded and reviewed off-line. In another embodiment, electrograms are reviewed by a processor within an implanted device after the electrograms are stored on memory within the implanted device.

The method described herein is used to analyze the electrograms to improve beat detection and to detect undersensing, oversensing, and noise.

Independent Event Sensing Algorithm

In one embodiment, electrograms from multiple channels are gathered. While data from many different channels can be used and compared, the following example discusses an algorithm using data gathered from the RV and shock channels. Furthermore, while this method may be performed in real-time, electrograms may also be analyzed off-line.

Removal of Far-Field Sensing

Removal of far-field sensing from a group of candidate beats is provided in one embodiment.

In one embodiment, the far-field removal is performed on cardiac electrogram data off-line rather than real-time. Performing the far-field removal off-line allows for the electrogram data to be run through and analyzed multiple times. Hence, the method is known as a “multi-pass” method. In each pass or data analysis run, each candidate beat is examined and different criteria are applied to remove candidate beats that should not be considered heart beats. One example of the multi-pass method **300** with two total passes is shown in FIG. **3**. FIG. **3** is flowchart showing an off-line method for analyzing cardiac electrogram data.

In step **310**, an electrogram is retrieved from a memory location **305** by a computer or other computing device. In step **320**, at least one channel from the electrogram is analyzed to identify a first-channel group of candidate beats. In a first embodiment, this channel is the atrial channel. In other embodiments, the ventricular or shock channels may be used. Next, in step **330**, at least one other channel from the electrogram is analyzed to identify a second-channel group of candidate beats. In the first embodiment, this channel is the ventricular channel. In other embodiments, this channel may be the atrial or shock channel. Processes for identifying candidate beats will be further described herein.

The first and second channels are then used in a multi-pass process for the purpose of removing far-field sensing. In a first pass **340**, a first pre-determined range is used to remove first-channel beat candidates. During the first pass **340**, the amplitude of each first-channel beat candidate is compared to the amplitude of both the previous and next first-channel beat candidate. Each first-channel beat candidate is evaluated to see if it meets the following criteria: the amplitude of a first-channel beat candidate is outside of a first pre-determined range from either the previous or the next beat and the first-channel beat candidate is near a second-channel beat candidate. In some embodiments, if the number of first-channel beat candidates which meet the criteria exceeds a first pre-defined beat count threshold, the first-channel beat candidates that meet the criteria are determined not to be a beat and removed. The pre-determined range is used to define acceptable thresholds for beat detection. In one embodiment, the first pre-determined range is between 20% to 200% of the amplitude from the previous beat or the next beat. In other embodiments, the first pre-determined range may be 10% to 250% of the amplitude from the previous or the next beat. A first-channel beat candidate is considered to be “near” a second-channel beat candidate if it occurs within a first time interval from the second-channel beat candidate. In one embodiment, that first time interval is 50 milliseconds. In other embodiments, that time interval is 100 milliseconds. The first pre-defined beat count threshold is used to define minimum number of beats that meet the pre-defined criteria. In one embodiment, the first pre-defined beat count threshold is 10% of the total number of beat candidates. In another embodiment, the first pre-defined beat count threshold is 5% of the total number of beat candidates.

In a second pass **350** of the multi-pass process, a second pre-determined range is used to further remove first-channel beat candidates. During the second pass **350**, the amplitude of each remaining first-channel beat candidate is compared to the amplitude of both the previous and next first-channel beat candidate. Each first-channel beat candidate is evaluated to see if it meets the following criteria: the amplitude of a first-channel beat candidate is outside of a second pre-determined range from either the previous or next beat and the first-

channel beat candidate is near a second-channel beat candidate. If the number of first-channel beat candidates which meet the criteria exceeds a second pre-defined beat count threshold, the first-channel beat candidates which meet the criteria are determined not to be a beat and removed. In one embodiment, the second pre-determined range is defined as beats with amplitudes that are between 40% to 180% of the amplitude of the previous candidate beat or the next candidate beat. In other embodiments, the second pre-determined range may be between 50% to 150% of the amplitude of the previous and next candidate beat. In one embodiment, the second pre-defined beat count threshold is 20% of the total number of beat candidates. In another embodiment, the second pre-defined beat count threshold is 30% of the total number of beat candidates.

Other embodiments of a multi-pass method for removal of far-field sensing are shown in FIGS. 4 and 5. In some embodiments, more than two passes are used in a multi-pass method, as shown in FIGS. 4 and 5. For example, in the multi-pass method 400 shown in FIG. 4, first 410 and second passes 420 are used followed by a third pass 430. After each of steps 410, 420, and 430, the number of identified beats is compared to a first, second, or third beat count threshold in steps 415, 425, and 435, respectively. In step 415, if the number of identified beats exceeds a first beat count threshold, then the identified beats are deleted. In step 425, if the number of identified beats exceeds a second beat count threshold, then the identified beats are deleted. In step 435, if the number of identified beats exceeds a third beat count threshold, then the identified beats are deleted.

In the multi-pass method 400, a memory 405 storing electrograms, pacing markers, first-channel beat candidates, and second-channel beat candidates provides data to be analyzed. The data is analyzed through the first 410 and second 420 passes, similar to the multi-pass method 300 of FIG. 3. In the third pass 430, a first-channel beat candidate is removed if it is near a second-channel beat and outside of a third pre-determined range from either the previous or next beat and near a second channel beat and the number of beat candidates which meet the criteria exceeds a third pre-determined beat count threshold. In one embodiment, the third pre-determined range is defined as between 80% and 120% of amplitude from the previous or next candidate beat. In other embodiments, the third pre-determined range may be defined as 70% or 130% of amplitude from the previous or next candidate beat. In one embodiment, the third pre-defined beat count threshold may be 40% of total number of beats. In another embodiment, the third pre-defined beat count threshold may be 50% of the total number of beats.

In the multi-pass method 500 shown in FIG. 5, an atrial channel is used as a first-channel, and a ventricular channel is used as a second-channel. A memory 505 provides storage for electrograms, pacing markers, atrial beat candidates and ventricular beat candidates to be analyzed. Similar to the embodiment shown in FIG. 4, the first pass 510 in FIG. 5 analyzes each sensed atrial candidate beat and removes sensed atrial candidate beats that are a) not within a first-pre-determined range of the previous and next atrial candidate beats and b) near a ventricular beat. In certain embodiments, certain passes may have one or more additional requirements that must be met before first-channel candidate beats are removed, as shown in the second pass 520 and third 530 pass in FIG. 5. For example, one pass may have a further requirement that there are at least a predetermined number of similar beats with similar first/second channel intervals in order for first-channel beat candidates to be removed, as with steps 520 and 530. The first/second channel interval is defined as the time differ-

ence between a first channel beat and the closest second channel beat. For example, in an embodiment where the first channel is an atrial channel and the second channel is a ventricular channel, shown in FIG. 5, the first/second channel interval is the AV interval, which is defined as the time difference between the atrial beat to the closest ventricular beat. In order for there to be a certain number of "similar" beats with similar AV intervals (or first/second channel intervals, generally), a similarity threshold is defined. The similarity threshold may be, for example, 5 milliseconds. In another embodiment, the similarity threshold may be 10 milliseconds. In such an embodiment, it may be required that there be, for example, three or more other atrial beats with similar AV intervals. As shown in the second pass 520 of FIG. 5, assuming the AV interval of the beat is x milliseconds, it is required then that more than three other atrial beats can be found, any of whose AV interval is within 10 milliseconds less than x and 10 milliseconds more than x. While FIG. 5 shows this requirement in the second pass, it may be a requirement of any or all of the passes of the multi-pass method.

A similar criterion is applied in the third pass 530, but the number of required similar beats is different. Before a candidate beat is removed, it is required that there are more than $N_v/2$ atrial beats with similar AV intervals, where N_v is defined as the total number of ventricular beats (or the total number of beats on the second channel, if another type of channel is used). Where the similarity threshold is 10 milliseconds and the AV interval of the beat is x milliseconds, it is required that more than $N_v/2$ other atrial beats can be found, any of whose AV interval is within 10 milliseconds less than x and 10 milliseconds more than x. While FIG. 5 shows this requirement in the third pass, it may be a requirement of any or all of the passes of the multi-pass method. Any combination of requirements may also be used, as shown in FIG. 5.

In another embodiment, a fourth pass is used (not shown), similar to the first, second, and third passes, wherein the first-channel beat candidate is removed if it is near a second-channel beat and outside of a fourth pre-determined range from either the previous or next beat. Other requirements may be used, as described above.

After each of steps 510, 520, and 530, the number of identified beats is compared to a first, second, or third beat count threshold in steps 515, 525, and 535, respectively. In step 515, if the number of identified beats exceeds a first beat count threshold, then the identified beats are deleted. In step 525, if the number of identified beats exceeds a second beat count threshold, then the identified beats are deleted. In step 535, if the number of identified beats exceeds a third beat count threshold, then the identified beats are deleted.

In an off-line evaluation of the detected beats, multiple passes (i.e. more than three or four, as described above) may be performed to improve the accuracy of the method. In such an embodiment, various pre-determined thresholds are used with varying degrees of restriction. In one embodiment, the pre-determined thresholds are stricter in later passes than in early passes. For example, in one embodiment, the second pre-determined range employs a threshold of the amplitude of the neighboring beats that is higher than a threshold of the amplitude of the neighboring beats that is employed in the first pre-determined range. In another embodiment, the second pre-determined beat count threshold is greater than the first pre-determined beat count.

The multi-pass method for removing far-field sensing may also be used in conjunction with other steps, including initial beat detection, noise removal, and detecting device oversensing or undersensing.

Beat Detection on an EGM Channel

The groups of candidate beats mentioned in the multi-pass methods described herein may be acquired using beat detection algorithms described herein. These groups of candidate beats originate from any EGM channel (i.e. right or left atrial, right or left ventricular, shock). The groups of candidate beats can be used for the first-channel group of candidate beats or second-channel group of candidate beats or any other channel group of candidate beats. In one embodiment, a particular group of candidate beats will originate from a single channel of an EGM.

A flow chart showing an example of beat detection sensing on one channel of an EGM **600** is shown in FIG. **6**. The method takes at least one channel from an EGM and pacing markers **605** from a memory storage location and analyzes the signal from the at least one channel to detect and collect a group of beats. First in step **610**, a first signal adaptive threshold is set. In one embodiment, the first signal adaptive threshold is set to 21 units. In another embodiment, the first signal adaptive threshold is set to 0.2 mV. The EGM channel data will be referred to as the signal S , where $S(i)$ is the signal value at a position i on the EGM channel signal. Next, at step **620**, at a position i , the absolute value of the signal $S(i)$ is tested to determine if it is a local maxima. If not, the method moves to step **624** and the signal at location i is determined not to be a beat. If the absolute value of the signal $S(i)$ is a local maxima, step **630** is performed at i to determine whether it is located within an estimated beat region. In one embodiment, the “estimated beat region” is defined as $0.8 < (i-p)/(p-q) < 1.2$, where p is the position of the previous beat, and q is the position of the beat occurring before p . In one embodiment, every data sample in the EGM is examined to determine whether it could be a beat location. In another embodiment, beat detection is performed on small (i.e. 100 ms), non-overlapping segments of the EGM.

An EGM **700** with three signal channels (atrial **710**, ventricular **712**, and shock **714**) is shown in FIG. **7**. An example estimated beat region for a particular position i is shown at portion **720** of the EGM ventricular channel **712**. Now referring back to FIG. **6**, if i is not located in the estimated beat region, the method moves to step **626** and $S(i)$ is analyzed to determine whether it is small noise. “Small noise” is identified if there is another signal whose absolute amplitude is larger than twice the absolute value of $S(i)$ within a small noise interval. In one embodiment, the small noise interval is 80 milliseconds. If $S(i)$ is a small noise, the method moves to step **624** and $S(i)$ is declared not to be a beat. If $S(i)$ is not a small noise, the method moves to step **628** and i is analyzed to determine whether it is located in a low amplitude region. A “low amplitude region” is identified when the magnitude of the maximum value (or the absolute value of the minimum value) within a certain interval, known as a low amplitude interval, is smaller than the first signal adaptive threshold. For example, a “low amplitude region” may be defined when the magnitude of the maximum value (or the absolute value of the minimum value) within the low amplitude interval is less than the signal adaptive threshold for the channel. That is, if the first signal adaptive threshold is 21 units, a low amplitude region is present if the magnitude of the maximum value (or the absolute value of the minimum value) within the low amplitude interval is less than 21. In one embodiment, the low amplitude interval is 400 milliseconds.

FIG. **7** also shows a portion of an EGM **730** with three signal channels (atrial **740**, ventricular **742**, and shock **744**). An example low amplitude region is shown at portion **750** of the ventricular channel **742** of the EGM. In this embodiment,

the low amplitude region is a 400 millisecond portion of the EGM **730** where i is at the center of the low amplitude region.

Again referring back to FIG. **6**, if $S(i)$ is a local maxima and in the estimated beat region, the method moves to step **640** and the first signal adaptive threshold is reset. For example, the first signal adaptive threshold may be reset to 33.3% of the amplitude of the previous beat. If the signal $S(i)$ is not small noise and i is located in a low amplitude region, then the method moves to step **632** and the first signal adaptive threshold is reset. In one embodiment, in step **632**, the first signal adaptive threshold is reset based on the maximal amplitude in the low amplitude region. For example, the first signal adaptive threshold may be reset to 95% of the maximal amplitude of the low amplitude region. In one embodiment, the low amplitude region may be 400 milliseconds. In either case, regardless of whether i is located in a low amplitude region, the absolute value of $S(i)$ is compared to the reset first signal adaptive threshold at step **650**. If the absolute value of $S(i)$ is not greater than the threshold, the method moves to step **624** and $S(i)$ is declared not to be a beat. If the absolute value of $S(i)$ is greater than the threshold, the algorithm moves to step **660** and determines whether the signal at $S(i)$ is paced and therefore caused by an artificial or device-induced shock. The determination of whether the signal at $S(i)$ is paced is based on the input pacing markers. If the signal at $S(i)$ is paced, $S(i)$ is not an intrinsic beat at step **624**. If $S(i)$ is not paced, then $S(i)$ is determined to be an intrinsic beat at step **670**.

While specific values are used to determine beats in the methods described herein, many other parameters may also be used. The values described above are presented as examples and are not meant to be limiting.

One alternative embodiment of the method used for initial beat detection **800** is shown in FIG. **8**. The method takes at least one channel from an EGM and pacing markers **805** from a memory storage location and analyzes the signals from the at least one channel to detect and collect a group of beats. First, in step **810** a signal adaptive threshold is set. In one embodiment, the threshold is set to 21 units. Then in step **820**, the absolute value of the signal $S(i)$ at position i is tested to determine whether it is a local maxima. If it is not a local maximal, the signal is determined not to be a beat at step **870**.

If $S(i)$ is a local maxima, step **830** tests the signal to determine if it is in a low amplitude region. A “low amplitude region” is identified when the magnitude of the maximum value (or the absolute value of the minimum value) within a certain interval, known as a low amplitude interval, is smaller than a signal adaptive threshold for a second rate channel. In one embodiment the second channel is the atrial channel. If the signal adaptive threshold is 21, a low amplitude region present if the magnitude of the maximum value (or the absolute value of the minimum value) within the low amplitude interval is less than 21. In one embodiment, the low amplitude interval is 400 milliseconds. If $S(i)$ is in a low amplitude region, the adaptive threshold is reset at step **835**. In one embodiment, in step **835**, the signal adaptive threshold is reset based on the maximal amplitude in the low amplitude region. For example, the first signal adaptive threshold may be reset to 66% of the maximal amplitude of the low amplitude region. In one embodiment, the low amplitude region may be 400 milliseconds.

In either case, the absolute value of $S(i)$ is tested to determine whether its value is greater than the adaptive threshold **840**. If not, $S(i)$ is not a beat **870**. If the absolute value of $S(i)$ is greater than the adaptive threshold, the algorithm determines whether the signal at $S(i)$ is paced **850** and therefore caused by an artificial or device-induced shock. If yes, $S(i)$ is

not an intrinsic beat **870**. If $S(i)$ is not paced, then $S(i)$ is an intrinsic beat **860** and is added to the group of candidate beats **880**.

To ensure all potential beats are identified, the adaptive threshold can also be adjusted to a lower value as described above. In one embodiment, it could be 70% of the threshold described above.

These methods of detecting heart beats on at least one channel output of a group of candidate beats can then be used in combination with the far-field sensing removal techniques described above. In one embodiment, the beat detection is performed first on the RA rate channel, and then the far-field sensing is removed from this channel.

Evaluation of Event Sensing by an IMD

FIG. **9** shows a method for performing independent, off-line evaluation of event sensing for collected electrograms **900**. An IMD **902** is used to sense EGM data **910**. The IMD **902** determines locations of heart beats within the EGM data, resulting in a group of device-identified beat locations **920**. These may also be known as device markers. Pacing markers may also be present within the EGM data, indicating when the IMD provided a pacing pulse to the patient's heart. For purposes of this discussion, pacing markers are not considered a type of device-identified beat locations. The EGM data and device-identified beat locations are then stored **930** in a memory location **904**. Next, a computer or other computing device such as a programmer is used to retrieve the EGM data and device-identified beat locations from the memory location **940**. The computing device determines the locations of heart beats on at least one channel of EGM data using a multi-pass process **950**. The group of beat locations determined using this multi-pass process is referred to as the multi-pass group of beat locations. The computing device then analyzes and compares the device-identified group of beat locations with the multi-pass group of beat locations **960**. Based on the comparison, the presence of oversensing, undersensing, or noise from the device can potentially be identified **970**.

One embodiment of the multi-pass process of step **950** is shown in the flow chart of FIG. **10**. In step **1010** of the multi-pass process **1000**, first a preliminary group of beat location candidates within the EGM is identified by the computing device. In a first pass **1020**, a portion of the preliminary group of beat location candidates is eliminated using a first algorithm, resulting in a refined group of beat location candidates. In a second pass **1030**, a portion of the refined group of beat location candidates is eliminated using a second algorithm, resulting in the group of multi-pass beat locations. The second algorithm is different than the first algorithm. For example, the second algorithm may implement the same formulas but utilize different parameters. Alternatively, the second algorithm may utilize the same parameters as the first algorithm but implement different steps. The multi-pass methods described above, such as those shown in FIGS. **3**, **4**, and **5** and described in the accompany text, may also be used in the method for performing independent, off-line evaluation of event sensing for collected electrograms **900**.

Undersensing/Oversensing/Noise Detection Results

After the number of detected beats is determined using the multi-pass methods described above, algorithms for detecting undersensing, oversensing, or CRM device noise may be implemented. These algorithms may be implemented off-line with previously recorded data. A comparison is made between the number of beats detected by the CRM device ("device-identified group of beats") and the number of sensed beats using the multi-pass methods described above ("multi-pass group of beats"). The multi-pass group of beats can be

from any channel of an EGM. If the number of device-identified beats is less than the number of beat candidates by a certain threshold, device undersensing is present.

For example, in one embodiment where the algorithm is performed off-line, if the CRM device identifies fewer than 80% of the beats detected using the multi-pass method, the CRM device may be undersensing. Similarly, if the CRM device senses more than 120% of the number of beats detected using the multi-pass method, the CRM device may be oversensing.

A comparison showing undersensing sensed by a CRM device versus a multi-pass algorithm is shown in FIGS. **11A** and **11B**. FIG. **11A** shows an EGM **1100** from a CRM device. FIG. **11B** shows output **1120** of the off-line multi-pass algorithm, where the same EGM **1100** of FIG. **11A** was used as input to the off-line multi-pass algorithm. The CRM device EGM **1100** shows signals from three channels: atrial **1102**, ventricular **1104**, and shock **1106**. Detected beats as determined by the CRM device are indicated along the bottom of the EGM using upward pointing arrows, such as arrow **1108**. The signal output **1120** from the off-line multi-pass algorithm also shows signals from the three channels: atrial **1122**, ventricular **1124**, and shock **1126**. Detected beats are indicated on the EGM with a cross mark, such as cross mark **1128** on each of the three channels.

As shown in the CRM device EGM **1100**, the CRM sensing misses a beat at EGM portion **1110** (no upward arrow is present to indicate a beat is detected) on the ventricular channel **1104**. In the off-line multi-pass algorithm output **1120** of FIG. **11B**, output portion **1130** corresponds to the same timeframe as EGM portion **1110** in FIG. **11A**. The off-line multi-pass algorithm detects the beat at portion **1130** on the ventricular channel **1124** as indicated by the cross mark in portion **1130**. In some algorithms, a certain number of beats of a certain type must be sensed before an episode is declared. As a result of missing the beat at **1110**, the device delayed declaring a ventricular fibrillation episode until a later beat was detected. The EGM **1100** in FIG. **11A** shows a declaration of a ventricular fibrillation episode at label **1109** at the bottom right corner of FIG. **11A**. However, if the beat at portion **1110** had been correctly sensed, an episode would have been properly declared at an earlier time. FIG. **11B** shows the beat that was missed at portion **1110** in FIG. **11A** properly sensed at portion **1130** and marked with a cross mark. As undersensing is avoided, episodes are less likely to be declared late.

If the number of device-identified beats is more than the number of beat candidates by a certain threshold, device oversensing is possible. A comparison showing oversensing and noise sensed by a device versus the presently disclosed algorithm is shown in FIGS. **12A** and **12B**. The CRM device EGM **1200** shows signals from three channels: atrial **1202**, ventricular **1204**, and shock **1206**. As with FIG. **11A**, detected beats in FIG. **12A** are indicated along the bottom of the EGM **1200** using upward pointing arrows. FIG. **12B** shows output **1220** from a multi-pass off-line detection algorithm, where EGM **1200** from FIG. **12A** was the input to the algorithm. Beats that are declared by the algorithm on FIG. **12B** are indicated on the output **1220** with a cross mark.

FIG. **12A** shows a number of detected beats in a portion **1210** of the EGM **1200** that are not in fact beats but rather the result of oversensing by the device. Portion **1230** on the algorithm output **1220** generally corresponds to the same timeframe as the position **1210** on the EGM **1200**. In portion **1230** of FIG. **12B**, there are no beats as determined by the algorithm. Portion **1230** of FIG. **12B** therefore shows over-

sensing by the device and shows no detected beats at portion **1230**. This evaluation can be performed over a complete EGM or for part of an EGM.

Noise in the CRM can be detected by checking the discrepancy in the number of beats detected by the CRM device and the number of sensed beats using the multi-pass methods described above. Discrepancies in the morphology, as described in common-assigned application Ser. No. 12/879, 147, the content of which is herein incorporated by reference, may also be compared to detect noise in the signal. When morphology is utilized to detect noise in the signal, the change in morphology is measured by the Euclidean distance.

Other methods can optionally be incorporated into the noise detection algorithm (e.g. prior to cross-channel/rate-shock comparison). For example, noise detection based on zero-crossing count may be used, as described in U.S. Pat. No. 6,917,830, the content of which is herein incorporated by reference. Alternatively, a signal saturation check based on determining the occurrence and number of max AD count value reached can be used to detect noise.

Sources of Cardiac Signal Data

Different cardiac rhythm management devices may be used to obtain EGM data from a patient. One example of a data-generating device is an implantable cardiac rhythm management device. Specific implantable cardiac rhythm management devices include a pacemaker, a cardioverter-defibrillator, a cardiac resynchronization device, a heart rhythm monitoring device, or the like. Other implantable data-generating devices include pressure sensors, heart sound sensors and impedance sensors. However, it is also possible to generate EGM data from external devices, including external pacemakers, external cardioverter-defibrillators, external resynchronization devices, external pressure sensors, external heart sound monitors and external impedance sensors. Additional examples of external devices that monitor cardiac activity include ambulatory electrocardiography devices or Holter monitors, which continuously monitor electrical activity of the heart for 24 hours or more. A data-generating device is one that is capable of providing cardiac signal information about an episode or time period experienced by a particular patient.

Many types of CRM devices communicate with devices located outside of the body, which can receive information from the implanted device including sensor information and information about events, such as when the implanted device has provided therapy. In some cases, the external interface device can also transmit operational parameters to an implanted CRM device, that is, program the device.

These external interface devices can be provided to a patient, often in a patient's home, and can collect information from the implanted device, and provide that information to a computer system designed to monitor the patient's status. An exemplary remote patient management system is the LATITUDE® patient management system, available from Boston Scientific Corporation, Natick, Mass. Aspects of exemplary remote patient management and monitoring systems are described in U.S. Pat. No. 6,978,182, the content of which is herein incorporated by reference in its entirety.

The existence of remote patient management systems such as the LATITUDE® patient management system has provided a large amount of data about patients with implanted medical devices. For example, these systems store patient sensor readings including EGM, pressure sensor signals, impedance signals and heart sound signals. The sensor readings can include information associated with arrhythmia episodes and other episodes experienced by the patient. These

systems also store information about patient characteristics, device settings and delivery of therapy by the device.

In one embodiment, a system and method uses this storehouse of patient-related data to analyze the device performance, understand a particular patient, understand a patient population group or improve therapy provided by the device. Such a system may operate outside of the device itself, such as on a server that is not at the same location as any of the data-gathering devices. As a result, a large amount of computer processing resources and memory can be devoted to utilizing the patient-related data.

“Episode” is defined to mean activity of a patient's body within a time period of particular interest. The time period can be a time when there is abnormal activity, for example, abnormal cardiac activity. “Episode data” is defined to include sensor readings from a medical data-generating device before, during and after the episode, and can also include device settings, actions that were taken by the device and other information. According to the system described herein, an episode database stores episode data about episodes that have occurred.

One or more data-generating devices can generate episode data. The episode database may have episode data about a plurality of episodes generated by one device, or generated by multiple devices. In one embodiment, the episode database is external to any of the data-generating devices. However, in another embodiment, the episode database is located within one of the data generating devices.

Storage and Use of the Episode Data and Characterization Data

The episode data or part of the episode data for a particular episode can be analyzed using a detection algorithm to detect undersensing, oversensing, or noise. Stored episodes comprising cardiac data are analyzed to collect potential beats as beat data. Beat data from different channels can be compared and analyzed to detect undersensing, oversensing, and noise. The beat data may be stored and associated with their respective episode data. The beat data may also be stored in an output database. In some embodiments, the beat data is sent to the data-generating device to be stored. Once undersensing, oversensing, or noise is detected, then it is possible to provide patients and clinicians with many different types of reports related to the episode data. It is also possible for the system to detect undersensing, oversensing, or noise that could be indicative of issues that need to be addressed by a health care provider. Alerts may be provided when an issue is detected. Programming recommendations may also be provided, for example, to adjust sensitivity, in response to detected oversensing or undersensing.

Description of Hardware Systems

The above-described method can be implemented on various hardware systems, such as on a programmer or in a patient management system. Alternatively, the method can be implemented on a computer or other computing device. Due to its low computational complexity, the method can also be implemented on implantable medical devices.

Further detailed embodiments of the hardware of the system will now be described with respect to the attached figures. The method may be applied to all device stored episodes and/or EGMs collected during regular monitoring sessions.

One embodiment of a data-generating device is a CRM device, as will now be described with reference to FIG. **13**, which is a schematic of an exemplary CRM system **1300**. The system **1300** can include an implantable medical device **1314** disposed within a patient **1312**. The implantable medical device **1314** can include pacing functionality. The implantable medical device **1314** can be of various types such as, for

example, a pacemaker, a cardioverter-defibrillator, a cardiac resynchronization device, a heart rhythm monitoring device, or the like. In some embodiments, the implantable medical device **1314** can include one or more leads **1322** disposed in or near the patient's heart **1326**.

The implantable medical device **1314** can be in communication with an external interface system **1316**. In some embodiments, communication between the implantable medical device **1314** and the external interface system **1316** can be via inductive communication through a wand **1310** held on the outside of the patient **1312** near the implantable medical device **1314**. However, in other embodiments, communication can be carried out via radiofrequency transmission, acoustically, or the like.

The implantable medical device **1314** can include one or more implantable sensors in order to gather data regarding the patient **1312**. For example, the implantable medical device **1314** can include an activity level sensor, a respiration sensor, a heart sounds sensor, a blood pressure sensor, an impedance sensor, or other sensors. The data gathered using the implantable medical device **1314** may be any type of patient data. In one embodiment, the implantable medical device **1314** collects electrograms from a patient. The patient data can further comprise data regarding the locations of heart beats within the electrograms. This data can be collected into groups of device-identified beat locations for each collected electrogram.

The implantable medical device **1314** can be configured to store data over a period of time, and periodically communicate with the external interface system **1316** in order to transmit some or all of the stored data.

The external interface system **1316** can be for example, a programmer, a programmer/recorder/monitor device, a computer, a patient management system, a personal digital assistant (PDA), or the like. As used herein, the term programmer refers to a device that programs implanted devices, records data from implanted devices, and allows monitoring of the implanted device. Exemplary programmer/recorder/monitor devices include the Model 3120 Programmer, available from Boston Scientific Corporation, Natick, Mass. The external interface system **1316** can include a user input device, such as a keyboard **1320** and/or a mouse **1328**. The external interface system **1316** can include a video output channel and video output device, such as a video display **1318** for displaying video output. The displayed video output can include a user interface screen. In addition, the video display **1318** can also be equipped with a touch screen, making it into a user input device as well.

The external interface device **1316** can display real-time data and/or stored data graphically, such as in charts or graphs, and textually through the user interface screen. In addition, the external interface device **1316** can present textual information to a user along with several response options. The external interface device **1316** can also input and store a user's response to a question, and can store a user's text response in some embodiments.

In one embodiment, the external interface device **1316**, which can also be referred to as a user interface, is in communication with a patient management computer system **1332**. The communication link between the user interface **1316** and the patient management computer system **1332** may be via phone lines, the Internet **1330**, or any other data connection. The user interface **1316** can also be used when it is not in communication with a device, but is only in communication with the patient management computer system **1332**.

In one embodiment, the external interface device **1316** is capable of changing the operational parameters of the

implantable medical device **1314**, and is therefore referred to as a programmer. Typically, programmers are used to interface with CRM devices in a clinic or hospital setting. In this context, the user of the external interface device is a physician or trained technician.

FIG. **14** is a schematic illustration of a patient management system consistent with at least one embodiment of the invention. The patient management system is capable of maintaining an episode database using computer storage medium. Of note, the episode database may also be present in an implantable or implanted device as discussed further herein. A computer storage medium is any technology, including devices and materials, used to place, keep and retrieve data. Examples of computer storage medium include random-access memory (RAM), a network-attached storage device, magnetic storage such as hard disk drives, optical discs, and a redundant array of independent discs (RAID). Patient management system **1400** generally includes one or more devices **1402**, **1404**, and **1406**, one or more external interface devices **1408**, a communication system **1410**, one or more remote peripheral devices **1409**, and a host **1412**. The host **1412** may be a single computing device, such as a programmer or other patient management device. In some embodiments, the host **1412** is an external device that communicates directly with the one or more devices **1402**, **1404**, and **1406** and does not require the use of separate external interface devices **1408**. In some embodiments, the host is an external device and receives data, such as EGM data, from an external database **1480**.

Each component of the patient management system **1400** can communicate using the communication system **1410**. Some components may also communicate directly with one another. The various components of the example patient management system **1400** illustrated herein are described below. The patient management system **1400** may be a single device or comprise multiple devices. In one embodiment, the patient management system **1400** is a single external computing device.

Data-generating devices **1402**, **1404**, and **1406** can be implantable devices or external devices that may provide one or more of the following functions with respect to a patient: (1) sensing, (2) data analysis, and (3) therapy. For example, in one embodiment, devices **1402**, **1404**, and **1406** are either implanted or external devices used to measure a variety of physiological, subjective, and environmental conditions of a patient using electrical, mechanical, and/or chemical means. The devices **1402**, **1404**, and **1406** can be configured to automatically gather data or can require manual intervention by the patient or another person. The devices **1402**, **1404**, and **1406** can be configured to store data related to the physiological and/or subjective measurements and/or transmit the data to the communication system **1410** using a variety of methods, described in detail below. Although three devices **1402**, **1404**, and **1406** are illustrated in the example embodiment shown, many more devices can be coupled to the patient management system. In one embodiment, each of the devices **1402**, **1404** and **1406** is serving a different patient. In one embodiment, two or more devices are serving a single patient.

The devices **1402**, **1404**, and **1406** can be configured to analyze the measured data and act upon the analyzed data. For example, the devices **1402**, **1404**, and **1406** can be configured to modify therapy or provide an alarm based on the analysis of the data.

In one embodiment, devices **1402**, **1404**, and **1406** provide therapy. Therapy can be provided automatically or in response to an external communication. Devices **1402**, **1404**, and **1406** are programmable in that the characteristics of their sensing, therapy (e.g., duration and interval), or communica-

tion can be altered by communication between the devices **1402**, **1404**, and **1406** and other components of the patient management system **1400**. Devices **1402**, **1404**, and **1406** can also perform self-checks or be interrogated by the communication system **1410** to verify that the devices are functioning properly. Examples of different embodiments of the devices **1402**, **1404**, and **1406** are provided herein.

Devices implanted within the body have the ability to sense and communicate as well as to provide therapy. Implantable devices can provide direct measurement of characteristics of the body, including, without limitation, electrical cardiac activity (e.g., a pacemaker, cardiac resynchronization management device, defibrillator, etc.), physical motion, temperature, heart rate, activity, blood pressure, breathing patterns, ejection fractions, blood viscosity, blood chemistry, blood glucose levels, and other patient-specific clinical physiological parameters, while minimizing the need for patient compliance. Derived measurements can also be determined from the implantable device sensors (e.g., a sleep sensor, functional capacity indicator, autonomic tone indicator, sleep quality indicator, cough indicator, anxiety indicator, and cardiovascular wellness indicator for calculating a quality of life indicator quantifying a patient's overall health and well-being).

Devices **1402**, **1404**, and **1406** can also be external devices, or devices that are not implanted in the human body, that are used to measure physiological data (e.g., a thermometer, sphygmomanometer, or external devices used to measure blood characteristics, body weight, physical strength, mental acuity, diet, heart characteristics, and relative geographic position).

The patient management system **1400** may also include one or more remote peripheral devices **1409** (e.g., cellular telephones, pagers, PDA devices, facsimiles, remote computers, printers, video and/or audio devices) that use wired or wireless technologies to communicate with the communication system **1410** and/or the host **1412**.

The database module **1414** comprises memory for storing patient data. The patient data can include electrogram data, which comprises groups of device-identified beat locations for the electrogram data. This data may be received from a patient device, such as an implantable medical device, or it may be retrieved from another database **1480**. The example database module **1414** includes a patient database **1444** and an episode database **1442**, which are described further below. The patient database **1444** includes patient specific data, including data acquired by the devices **1402**, **1404**, and **1406**, such as electrogram data, as well as a patient's medical records and historical information. The episode database **1442** has episode data regarding a plurality of different episodes generated from those of devices **1402**, **1404**, and **1406** that provide episode data. The episode database **1442** may also store data analyzed by the analysis module **1416**.

Information can also be provided from an external source, such as external database **1480**. For example, the external database **1480** could include external medical records maintained by a third party, such as drug prescription records maintained by a pharmacy, providing information regarding the type of drugs that have been prescribed for a patient or, in another example, authorization data from patient groups that have authorized users to view arrhythmia episode data. The external database **1480** may also store patient data that was previously acquired by an implantable or external medical device. One example of stored patient data on an external database **1480** is electrogram data.

The example analysis module **1416** includes a patient analysis module **1450** and a device analysis module **1452**.

Patient analysis module **1450** may utilize information collected by the patient management system **1400**, as well as information for other relevant sources, to analyze data related to a patient and provide timely and predictive assessments of the patient's well-being. Device analysis module **1452** analyzes data from the devices **1402**, **1404**, and **1406** and external interface devices **1408** to predict and determine device issues or failures. For example, the device analysis module **1452** may analyze electrogram data to determine locations of heart beats on one or more channels using the multi-pass methods described above. The device analysis module **1452** can further compare device-identified beats and beat locations to beats and beat locations determined using the multi-pass method. The device analysis module **1452** can then perform comparisons to find the presence of noise, oversensing, and undersensing by the device, as described above.

The analysis module **1416** further includes an adjudication processor **1458**, and episode processor **1460** and an overwrite processor **1462**. In one embodiment, the adjudication processor is operatively connected to at least the episode database **1442** and is configured to receive as input episode data regarding one of the different episodes.

The episode processor **1460** performs processing of the adjudication database such as in order to provide reports, patient alerts, or programming recommendations. The overwrite processor **1462** can analyze data provided from the episode database **1442**, and other portions of the patient management system **1400** to determine what particular portion of episode data for one of the episodes from the episode database should be displayed to a user. Overwrite processor **1462** can, through the delivery module **1418** described below, provide the means for graphically displaying a portion of data selected from arrhythmia episode data related to an episode of a patient, such as data generated by a data-generating device and stored in the episode database.

Overwrite processor **1462** also requests from a user any changes in the characterization data determined by the adjudication processor, and can articulate the request for user input characterizing an episode. The request may be a direct question to a user, a series of choices provided to the user, or simply a blank space on the user interface configured to accommodate the user input. The overwrite processor **1462** may also store the overwrite history for individual users.

One or more portions of the analysis module **1416**, such as the adjudication processor **1458** and episode processor **1460** may be located remotely from other parts of the patient management system **1400**. A microprocessor of a data-generating device may also serve as an adjudication processor in some embodiments.

Delivery module **1418** coordinates the delivery of reports, patient alerts or programming recommendations based on the analysis performed by the host **1412**. For example, based on the data collected from the devices and analyzed by the host **1412**, the delivery module **1418** can deliver information to the caregiver, user, or to the patient using, for example, a display provided on the external interface device **1408**. A user interface device **1490** that is independent of a data-generating device may also be used to deliver information. The external interface device **1408** and user interface device **1490** are also configured, according to multiple embodiments, to display a report, alert, or programming recommendation, receive overwrite information from a user, and receive other data from the user. Displayed data, as described above, can be determined by the episode processor **1460**, overwrite processor **1462** and delivery module **1418**.

External interface devices **1408** to display information, such as programmer/recorder/monitors, can include compo-

nents common to many computing devices. User interface devices **1490** to display and received information from users can also include components common to many computing devices. Referring now to FIG. **15**, a diagram of various components is shown in accordance with some embodiments of the invention. However, it is not required that an external interface device have all of the components illustrated in FIG. **15**.

In one embodiment, the external interface device includes a central processing unit (CPU) **1505** or processor, which may include a conventional microprocessor, random access memory (RAM) **1510** for temporary storage of information, and read only memory (ROM) **1515** for permanent storage of information. A memory controller **1520** is provided for controlling system RAM **1510**. A bus controller **1525** is provided for controlling data bus **1530**, and an interrupt controller **1535** is used for receiving and processing various interrupt signals from the other system components.

Mass storage can be provided by diskette drive **1541**, which is connected to bus **1530** by controller **1540**, CD-ROM drive **1546**, which is connected to bus **1530** by controller **1545**, and hard disk drive **1551**, which is connected to bus **1530** by controller **1550**. User input to the programmer system may be provided by a number of devices. For example, a keyboard and mouse can connected to bus **1530** by keyboard and mouse controller **1555**. DMA controller **1560** is provided for performing direct memory access to system RAM **1510**. A visual display is generated by a video controller **1565** or video output, which controls video display **1570**. The external system can also include a telemetry interface **1590** or telemetry circuit which allows the external system to interface and exchange data with an implantable medical device. It will be appreciated that some embodiments may lack various elements illustrated in FIG. **15**.

Referring now to FIG. **16**, some components of an exemplary implantable medical device **1600** are schematically illustrated. The implantable medical device **1600** can include a controller made up of a microprocessor **1610** communicating with a memory **1612**, where the memory **1612** may comprise a ROM (read-only memory) for program storage and a RAM (random-access memory) for data storage. The controller could be implemented by other types of logic circuitry (e.g., discrete components or programmable logic arrays) using a state machine type of design, but a microprocessor-based system is preferable. The controller is capable of operating the implantable medical device **1600** in a number of programmed modes where a programmed mode defines how pacing pulses are output in response to sensed events and expiration of time intervals.

A telemetry interface **1680** is provided for communicating with an external programmer **1675**. The external programmer is a computerized device with a controller **1677** that can interrogate the implantable medical device **1600** and receive stored data as well as adjust the operating parameters of the pacemaker.

The implantable medical device **1600** has an atrial sensing/pacing channel comprising ring electrode **1633A** tip electrode **1633B** sense amplifier **1631**, pulse generator **1632**, and an atrial channel interface **1630** which communicates bidirectionally with a port of microprocessor **1610**. The device also has two ventricular sensing/pacing channels that similarly include ring electrodes **1643A** and **1653A** tip electrodes **1643B** and **1653B** sense amplifiers **1641** and **1651**, pulse generators **1642** and **1652**, and ventricular channel interfaces **1640** and **1650**. For each channel, the electrodes are connected to the implantable medical device **1600** by a lead and used for both sensing and pacing. A MOS switching network

1670 controlled by the microprocessor is used to switch the electrodes from the input of a sense amplifier to the output of a pulse generator. A shock channel is also provided comprising a shock pulse generator **1690** and shock electrodes **1691A** and **1691B** that enables the device to deliver a defibrillation shock to the heart when fibrillation or other tachyarrhythmia is detected. The implantable medical device **1600** also has an evoked response sensing channel that comprises an evoked response channel interface **1620** and a sense amplifier **1621** that has its differential inputs connected to a unipolar electrode **1623** and to the device housing or can **1660** through the switching network **1670**. The evoked response sensing channel may be used to verify that a pacing pulse has achieved capture of the heart in a conventional manner or, as explained below, used to record an evoked response electrogram.

The channel interfaces include analog-to-digital converters for digitizing sensing signal inputs from the sensing amplifiers, registers that can be written to for adjusting the gain and threshold values of the sensing amplifiers, and, in the case of the ventricular and atrial channel interfaces, registers for controlling the output of pacing pulses and/or adjusting the pacing pulse energy by changing the pulse amplitude or pulse width. The microprocessor **1610** controls the overall operation of the device in accordance with programmed instructions stored in memory. The sensing circuitry of the implantable medical device **1600** generates atrial and ventricular sense signals when voltages sensed by the electrodes exceed a specified threshold. The controller then interprets sense signals from the sensing channels and controls the delivery of paces in accordance with a programmed pacing mode. The sense signals from any of the sensing channels of the implantable medical device **1600** in FIG. **16** can be digitized and recorded by the controller to constitute an electrogram that can either be transmitted via the telemetry link **1680** to the external programmer **1675** or stored for later transmission. The patient's cardiac activity may thus be observed in real-time or over a selected historical period.

The above-described method can be regularly initiated to evaluate the sensing performance of the medical device. Additionally, the method can also be triggered by events, such as when ventricular arrhythmia episodes are detected, when mode switch due to atrial arrhythmias occurs, and when atrial arrhythmia episodes are detected. When issues are detected, the device may store the electrogram and provide to physician for review. Programming recommendations may also be made. In some instances, arrhythmia therapy may be withheld due to detection of issues. Gathered data may be used as input for other device functionality, such as arrhythmia adjudication.

It should be noted that, as used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the content clearly dictates otherwise. It should also be noted that the term "or" is generally employed in its sense including "and/or" unless the content clearly dictates otherwise.

It should also be noted that, as used in this specification and the appended claims, the phrase "configured" describes a system, apparatus, or other structure that is constructed or configured to perform a particular task or adopt a particular configuration. The phrase "configured" can be used interchangeably with other similar phrases such as "arranged", "arranged and configured", "constructed and arranged", "constructed", "manufactured and arranged", and the like.

One of ordinary skill in the art will understand that the modules, circuitry, and methods shown and described herein with regard to various embodiments of the invention can be implemented using software, hardware, and combinations of

software and hardware. As such, the illustrated and/or described modules and circuitry are intended to encompass software implementations, hardware implementations, and software and hardware implementations.

All publications and patent applications in this specification are indicative of the level of ordinary skill in the art to which this invention pertains. All publications and patent applications are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated by reference.

This application is intended to cover adaptations or variations of the present subject matter. It is to be understood that the above description is intended to be illustrative, and not restrictive. The scope of the present subject matter should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

The invention claimed is:

1. A method for performing and evaluating independent, off-line event sensing for collected electrograms, comprising:
 sensing an electrogram using an implantable medical device (IMD);
 the IMD determining locations of heart beats within the electrogram, resulting in a group of device-identified beat locations for the electrogram;
 storing the electrogram and device-identified beat locations in a memory location;
 retrieving, by an external computing device, the electrogram and device-identified beat locations from the memory location;
 after retrieving the electrogram from the memory location, determining, by the external computing device, locations of heart beats on at least a first channel of the electrogram using a multi-pass process, resulting in a group of multi-pass beat locations, wherein the multi-pass process comprises:

identifying a preliminary group of beat location candidates within the first channel of the electrogram;

eliminating a portion of the preliminary group of beat location candidates using a first algorithm resulting in a refined group of beat location candidates, wherein the first algorithm comprises comparing the amplitude of each of the preliminary beat location candidates with a first signal adaptive threshold; and

eliminating a portion of the refined group of beat location candidates using a second algorithm resulting in the group of multi-pass beat location candidates, wherein the second algorithm comprises comparing the amplitude of each of the preliminary beat location candidates with a second signal adaptive threshold; and

comparing the device-identified group of beat locations to the multi-pass group of beat locations identified using the multi-pass method.

2. The method of claim **1**, wherein at least one of the first and second algorithms further comprises determining whether each of the preliminary beat location candidates is small noise.

3. The method of claim **1**, wherein determining locations of heart beats is on at least the first channel and a second channel of the electrogram, wherein the first channel of the electrogram is an atrial channel and the second channel of the electrogram is a ventricular channel.

4. The method of claim **3**, further comprising identifying oversensing of beats, undersensing of beats, or noise from the device based on the comparing of the device-identified group of beat locations to the multi-pass group of beat locations.

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